Ontario

Advisory Council on Occupational Health and Occupational Safety

Fourth Annual Report

April 1, 1981
to March 31, 1982

Mandate and Objectives

The function of the Advisory Council is and it has power to*:

a) make recommendations to the Minister of Labour relating to programs of the ministry in occupational health and occupational safety; and

b) advise the minister on matters relating to occupational health and occupational safety which may be brought to its attention or be referred to it.

To achieve this Council has set the following objectives:

Primary Objective
To advise the Minister of Labour on all matters relative to occupational health and safety in Ontario.

Secondary Objectives

1. To ensure as far as possible that the policies and programs in occupational health and safety effectively minimize the risks to health and safety in all workplaces in Ontario.
2. To ensure as far as possible that knowledge about occupational health and safety is available to management, labour and the public and that it is understood by them.
3. To assist in promoting and establishing mechanisms involving management and labour to solve problems in occupational health and safety.
4. To ensure as far as possible that there is appropriate manpower training and development for the occupational health and safety field.
5. To review periodically the effectiveness of the policies and programs implemented to achieve objectives 1 to 4.**

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*The Occupational Health and Safety Act, s 10(7).
**added June, 1980.

Advisory Council on Occupational Health and Occupational Safety

Fourth Annual Report
April 1, 1981
to March 31, 1982

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Toronto, Ontario
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Ontario

Advisory Council on
Occupational Health &
Occupational Safety

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of the
Chairman

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File: AC/A/14

April 30, 1982

The Honourable R.H. Ramsay
Minister of Labour
400 University Avenue
14th Floor
TORONTO, Ontario
M7A 1T7

Sir:

I have the honour to submit the Fourth Annual Report of the Advisory Council on Occupational Health and Occupational Safety for the fiscal year 1981-82.

I have the honour to be, Sir,

Your obedient servant

J. F. Mustard

Chairman

Attachment

Advisory Council on Occupational Health and Occupational Safety Members and Officers 1981-82

W.A. Barnes (1983)
General Motors of Canada
St. Catharines

Mrs. N. Caldbick (1982)
Housewife
Timmins

Dr. J.W. Charters (1983)
Steel Company of Canada
Hamilton

J. Duffy (1982)
Provincial Building and Construction Trades Council
Don Mills

J.C. Fisher* (1982)
Shell Oil Sarnia Mfg. Centre
Corunna

P.A. Fisher (1983)
Fisher Farms
Burlington

Dr. R.D. Fraser (1982)
Queen's University
Kingston

J. Gill (1982)
United Automobile Workers
Willowdale

L. Heard (1983)
United Steelworkers of America
Toronto

M. Kellow (1983)
Abitibi Price
Toronto

Dr. E. Mastromatteo (1982)
INCO Limited
Toronto

J.M. More (1983)
Energy and Chemical Workers' Union
Oakville

Dr. J.F. Mustard (1983)
Chairman
McMaster University
Hamilton

C.G. Pilkey (1983)
Ontario Federation of Labour
Don Mills

G.J. Samson (1982)
Safety Consultant
Toronto

Dr. G.J. Stopps (1983)
University of Toronto
Toronto

M.A. Taschereau (1983)
Dome Mines
Toronto

E.A. Waddell (1983)
Ontario Federation of Labour
Don Mills

R. Wilson (1982)
Ontario Hydro
Toronto

Dr. A.D. Wolfson (1982)
Vice-Chairman
University of Toronto
Toronto

Mrs. V. Biggar
Research Officer

A.J. Byrne
Executive Secretary

Mrs. E. Harney
Executive Assistant

I.S. Glasberg
Research Officer

Miss G. Perry**
Research Officer

N.R. Subramanian
Committee Officer

Members' terms expire on October 31 of the year indicated in parentheses.

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* – Resigned December 1981.

** – Joined staff February 1982.

Preface

In last year's annual report, council commented on the first of a planned series of meetings and discussions, in different regions of the province, with representatives of management and labour. The purpose of these meetings is to give council the opportunity to seek from management and members of the work force their views on how effectively the provisions of the *Occupational Health and Safety Act* are being implemented. Continuing this experiment, council went to the Kitchener region in November 1981 and met with labour and management representatives from local industry. The meetings were productive in that they gave council members an opportunity to hear the opinions of both sides, which were sometimes at variance, but more often revealed a genuine determination by all parties to find solutions to health and safety problems. The meetings were, however, disappointing to the extent that council was not able to meet with representatives from small firms in the area. The current economic problems faced by industry in general place particularly severe restraints on small businesses in terms of the time and money which can be devoted to 'extramural' activities. Council understands these difficulties and will, in the future, approach small firms and their employees to solicit their comments on the implementation of the Act in a way which will be less disruptive of normal business activities.

The financial difficulties which will undoubtedly be experienced by some small companies in meeting the provisions of the designated substance regulations are discussed in Advisory Memorandum 81-IV on the subject of Financial Incentives in the Occupational Health and Safety field.

Partly as a result of its two field trips, council decided that it would be appropriate to make a more organized and in-depth study of the implementation of the Act, almost three years after its enactment. A task force has been set up to review the application and interpretation of the Act and regulations, to examine the functioning of joint health and safety committees and to review the implementation of the designated substance regulations.

In a slightly different context, during the past year, council has been called upon by the minister to monitor and review the procedures followed during the development of the designated substance regulations. The first two such regulations, for lead and mercury, were promulgated this year and council's comments on the procedures followed are to be found in Advisory Memoranda 81-I and 81-III. Table 1 on page 12 shows the various stages of council's involvement, and gives an indication of the time frames involved in this process.

It has been council's impression to date that the ministry has approached the difficult task of formulating designated substance regulations with a commendable degree of openness. However, in the course of its study of the procedural aspects, council has become aware of the understandable difficulties which ministry staff have encountered in their analysis of the volumes of complex data and background material relating to each of the designated substances. Council has struck a task force with a view to advising the minister on the interpretation of health effects data and the role of economic analysis in the standard-setting process.

One of the complex issues which has been brought to council's attention in the course of its examination of the analytical processes leading to a designated substance regulation, has been the question of whether different standards should be set for women capable of bearing children. This is one of the issues which will be discussed by the Task Force on Women and Occupational Health and Safety, which will report later this year.

A subject of very current concern to many sectors of the work force is that of the possible health hazards connected with visual display units. A task force of council will present a report in the coming months.

The Special Task Group on the Role of the Safety Associations brought in its report this year and council offered its advice to the minister in the form of Advisory Memorandum 81-II. The letter which accompanied this Advisory Memorandum, dated November 4, 1981, and a subsequent letter dated February 11, 1982, are drawn to the reader's attention in the hope that a careful examination of their contents will eliminate any misunderstandings about the intent of the advisory memorandum. Council is sensitive to the concerns and apprehensions felt by those groups and individuals whose interests would be most immediately affected by any change of policy in this area. Indeed, in its letter of November 4, 1981, council urged the minister to consult with all groups that would be affected by the implementation of any of the proposals contained in the advisory memorandum. All those who have concerns are encouraged to take advantage of the consultative process, which council understands has already been initiated by the ministry.

One of the most difficult challenges to which council has been asked to respond in recent years is that of advising the minister on a regulatory policy for carcinogens. A substantial report prepared for council by a special advisory group of experts in this field is contained in this annual report, starting at page 141. A discussion paper putting forward one possible approach with respect to the indentification, classification and regulation of workplace carcinogens will be distributed by council early in the coming year. Responses will be invited from all interested parties, after which, council will prepare its advisory memorandum to the minister.

Council expects to offer advice to the minister in the following areas also:

- The role of health surveillance and health screening in occupational health programs.
- Potential new hazards.
- Literacy and occupational health and safety.

The final section of this year's annual report contains administrative matters. The advisory council is governed by section 10 of the *Occupational*

Health and Safety Act, which has been reproduced in full for easy reference. The council's objectives and terms of reference are also set out in this section, as well as dates of council meetings and the terms of reference, membership and meeting dates of its task forces.

An appendix is included at the end of the report. It contains a variety of statistics on occupational fatalities, major disabilities, injuries and illnesses in Ontario. Council wishes to acknowledge the contribution of Mr. Peter Lewycky of the ministry's Research Branch who, each year, provides council with these statistics.

Council is, as ever, indebted to all those members of its task forces who, though not members of council itself, have devoted unlimited time, energy and enthusiasm to assisting it in the preparation of its advice to the minister. Without their continuing support, council would not be in a position to fulfil its responsibilities.

The assistance provided by all those government and private organizations which have supplied council's staff with the information needed by the task forces is also gratefully acknowledged.

It is with regret that council announces the resignation of Mr. John Fisher. Council wishes to thank him for his sincere and thoughtful contributions to its past endeavours.

Table 1

The Development of the Designated Substance Regulations — The Advisory Council's Involvement in the Process

Lead

April 27, 1981	Council received the third draft of the regulation.
May 15, 1981	Council sent an interim letter to the minister, commenting on various aspects of the process leading to the draft regulation.
June 3, 1981	The minister replied to council's interim letter.
July 9, 1981	Council submitted Advisory Memorandum 81-I 'A Review by the Advisory Council of the Process Used to Develop a Standard for Lead and Council's Evaluation of the Criteria Utilized to Assess the Hazard of Lead Exposure in the Workplace.'
August 11, 1981	The minister replied to Advisory Memorandum 81-I. (The lead regulation was filed with the Registrar of Regulations, August 14, 1981.)

Mercury

July 17, 1981	Council received the third draft of the regulation.
August 27, 1981	Council sent an interim letter to the minister, commenting on various aspects of the process leading to the draft regulation.
November 20, 1981	Council received the minister's reply to the interim letter, together with a fourth draft of the regulation.
December 10, 1981	Council submitted Advisory Memorandum 81-III, 'A Review by the Advisory Council of the Process Used to Develop a Standard for Mercury and Council's Evaluation of the Criteria Utilized to Assess the Hazard of Mercury Exposure in the Workplace'.
February 9, 1982	The minister replied to Advisory Memorandum 81-III. (The mercury regulation was filed with the Registrar of Regulations, March 9, 1982.)

INTRODUCTION

The Prevention of Occupational Accidents and Diseases: Some Recent Trends and Possible Future Developments

In the introduction to its First Annual Report, council emphasized that one's lifestyle and the environment in which one lives and works are major determinants of human health.[1] Council also stated at that time that the workplace is an example of a sector where the physical environment can be controlled to influence health. Council believes that the views set out in its first introduction are equally valid today, and that future gains in human health will depend largely on changes in lifestyle and improvements to the environment. This introduction will build on the principles enunciated in council's previous documents by presenting some relevant data on traumatic injuries and disease in the workplace and by reviewing recent trends in the accident and disease prevention fields. The second portion of the introduction will then consider the potential impact that new knowledge and advanced technology could have on the control of health hazards in the workplace.

Some General Statistics

Research conducted into the areas of premature death and illness indicates that for men and women aged 18 to 44, accidents account for the greatest single source of fatalities.[2] In 1978, 5,284 Canadians in this age category died as a result of injuries sustained in accidents. Although motor vehicle accidents contributed the largest single element to this total (3,241 deaths), industrial accidents were also an important source of mortality, being responsible for 345 deaths. In 1971 alone, Canadians lost 392,000 years of potential life because of traumatic injuries.[3] By contrast, an estimated 193,000 years were lost in the same 12-month period as a result of heart attacks, and an additional 140,000 years were lost because of lung cancer and other respiratory diseases.[4] Since trauma produces such an enormous impact on the most productive years of life, any preventive measures designed to reduce the frequency of traumatic injuries will be extremely beneficial.

Individuals in modern industrialized societies may also run the risk of being exposed to potentially harmful agents in the air they breathe and in the food and water they ingest. There also exists a spectrum of workplace hazards, which could produce such ailments as dermatitis, noise-induced hearing loss, lung disease (e.g. asbestosis and silicosis), injuries to the cornea and metal poisoning (e.g. through exposure to such substances as lead and mercury).

As individuals grow older, cancer becomes a major cause of death. Studies conducted by Doll and Peto have indicated that approximately 75 to 80 per cent of all cancer cases recorded in the United States, among men and women, aged 65 or less, are caused by environmental and lifestyle factors.[5] These types of malignancies are classified by the authors as 'avoidable cancers'. There is an accumulating body of knowledge to suggest that some types of cancer, which develop in later life, can be traced back to events which occurred many years in the past. For example, a case of lung cancer that was caused by exposure to asbestos may not develop until 25 to 30 years after the first exposure to the fibre. Because latency periods can be so long, it often becomes difficult to determine what events or exposures were responsible for tumour development.

The Occupational Environment

1. *Cancer in the Workplace*

Although many substances found in the workplace can create health problems, if not properly controlled, one must be especially concerned about the effects of workplace carcinogens. That is the case because low levels of exposure to these agents can lead ultimately to premature death. While it is well established that exposure to carcinogens in the workplace contributes to the incidence of cancer in the population, there is some debate on the percentage of total cancers that are attributable to occupational exposures. In this respect, Doll and Peto, while acknowledging that uncertainty exists in the area, have estimated that four per cent of all cancer deaths in the US population (with a possible range between two and eight per cent) are caused by factors in the workplace environment.[6] This percentage figure would be higher, however, if the working population, rather than the total population, were considered. A paper submitted to the US Occupational Safety and Health Administration (OSHA) by the National Cancer Institute *et al* suggests, on the other hand, that from 23 to 38 per cent of all the cancer deaths in the United States may be occupationally induced.[7] The OSHA paper has been criticized, however, because the document takes into account neither the duration nor the degree of worker exposure to workplace carcinogens.[8] In the same vein, the four per cent estimate advanced by Doll and Peto may be overly conservative, in that workplace carcinogens may react synergistically with other factors (e.g. cigarette smoke, alcohol) to produce cancers that are not placed into the occupational category.

The latest statistics available for Ontario indicate that 13,390 persons (7,320 males and 6,070 females) over the age of 24 died of cancer in the province in 1978.[9] If one applies the conservative Doll and Peto estimate to this figure, there is the possibility that 536 workers could have died in that year as a result of workplace exposure to carcinogens.[10] By contrast, the Ontario Workmen's Compensation Board (WCB) reported 41 occupationallly induced cancers for 1978 (the figures recorded for 1979 and 1980 were 66 and 64 respectively).[11] The rather large discrepancy between the Doll and Peto estimate, on the one hand, and the WCB totals, on the other hand, could mean that the former approximation is unrealistically high. Alternatively, given the fact that many types of workplace cancers are indistinguishable from malignancies induced by other factors, there is the possibility that a proportion of occupationally induced tumours may not be recognized as having originated in the workplace. As a result, claims for compensation would not be submitted to the WCB.

It should be recognized that, for the most part, workers do not voluntarily choose to come into contact with carcinogens at their job sites. It is usually the case that, because of a lack of knowledge, appropriate information or alternative job opportunities, workers are compelled to accept some degree of exposure risk. This state of affairs may be contrasted to the situation where an individual decides voluntarily to expose himself or herself to a carcinogen (e.g. by accepting a wage premium or by smoking).

It is difficult to accept, as a matter of principle, that any worker should face the risk of dying from an occupationally induced cancer where the agent that causes the disease can be satisfactorily controlled. On the basis of evidence which suggests that the modification of lifestyle factors (e.g. smoking) can reduce the incidence of some types of cancer in the general population, the stringent control of carcinogens in a closed workplace environment should reduce the number of malignancies that are thought to be occupationally induced. In this regard, the use of engineering controls to prevent exposure to carcinogens in the workplace is becoming increasingly feasible and should be made a priority in occupational health programs. It might be noted, in this respect, that several industries have already developed processes for the handling of carcinogenic materials that have virtually eliminated human exposure to these agents.[12]

Although workplace carcinogens account for only a portion of premature cancer deaths in Ontario, strategies devised to control these agents in the occupational environment could serve as models to reduce other types of cancer risks, and to control other sorts of harmful exposures.

2. *Occupational Accidents*

Occupational accidents also take a serious toll in the province. Statistics indicate that 187 fatalities have resulted from traumatic injuries that were first compensated in 1980.[13] At the outset, Canadians apparently tend to have more accidents than citizens of other developed countries. This proposition was documented in a 1978 World Health Organization[14] survey of accidents by major causes for males in 27 countries. The survey indicated that Canadian males ranked 23rd overall and 25th for accidents that were mostly industrial in nature. Several factors, including geography, economic structure, population concentration, technological infrastructure, age distribution and attitude towards risk, have been put forward in an attempt to explain why the general rate of accidents in this country is so high.[15] Whatever factors are thought to be paramount, however, it is probably true that attitudes and lifestyle factors contribute to at least some accidents. In this respect, the process of identifying the causes of different types of accidents can become extremely difficult.

In the last decade, technical advances have made it possible to isolate and control many of the factors that contribute to accidents and disease in the workplace. In the accident prevention field, comprehensive investigation techniques (such as the Management Oversight and Risk Tree (MORT))[16] have been developed to analyse accident causation in a detailed and systematic fashion. In addition, new workplace evaluation and accreditation programs such as the Industrial Accident Prevention Association's Five Star Rating System, are now available to assist in the identification of equipment and processes that could pose potential risks to workers. Organizations such as the Construction Safety Association of Ontario (CSAO) have developed comprehensive computer based data systems in an attempt to isolate factors that are regularly associated with accidents. The CSAO employs the information obtained from its system to determine which firms require special help from CSAO consultants, and to identify worksite activities that produce disproportionately high accident rates. On the basis of statistics derived from its computer system, the CSAO has learned that mounting and dismounting injuries involving heavy equipment are particularly common. As a result, the organization has developed a program to reduce the number of accidents connected with this type of work activity.

It should also be noted that the continuing application of the science of ergonomics to occupational hazards (with its premise that machinery must be designed to meet the requirements of the operator, and not *vice versa*) should reduce accident rates in those establishments where ergonomic design considerations have been adopted.

It would appear that a systematic reduction of accidents in this jurisdiction is unlikely to occur unless additional resources are committed for accident investigations, worker training, workplace inspections and the application of ergonomic principles to the worksite. The speed at which these programs can be developed will depend on such factors as attitudes, understanding, resources, incentives and the commitment of labour, management and government to the goal of a safer workplace.

In Advisory Memorandum 80-IV,[17] the advisory council put forward several recommendations that it believed would result in the long-term reduction of accident and disease rates in the workplace. In respect to accident prevention, council proposed that greater emphasis be placed on a) the identification of industries and occupational groups exhibiting high injury and fatality rates, and b) the detailed investigation of particular categories of accidents for cause. In this memorandum, council also stressed that a cost-effective accident prevention program must concentrate on investigating those accidents which produce the greatest amount of human injury and disability. In order to achieve this goal, council recommended that the appropriate authorities encourage the development of a three-tiered system for the collection and interpretation of accident data. Tier 1 would consist of a framework for the collection of general information about accidents, with emphasis on the identification of industries and occupational groups experiencing disproportionately high injury and fatality rates; tier 2 would include procedures designed to elicit more selective and complex data in respect to the most accident-prone industries and occupations; while tier 3 would encompass procedures for the detailed, causal investigation of selected accident types that are responsible for the greatest amount of injury and disability. A tier 3 investigation could focus on faults within work management systems (i.e. deficiencies in respect to procedures, hardware, work organization and the workplace environment). It was also council's view that an improved data base was necessary in order to undertake more comprehensive studies on accident causation.

Council is pleased to note that several organizations are currently reviewing and analysing accident data in order to identify trends and patterns. The Construction Safety Association of Ontario (CSAO) has determined, for example, that during the period from 1976 to 1980, demolition workers exhibited the highest fatality frequency per million man-hours worked of any occupational group involved in the construction field.[18] The actual rate was 1.40 fatalities per million man-hours worked (calculated on the basis of four fatalities over a period of 2,866,000 man-hours). The next highest rate recorded in the construction industry was 0.84 fatalities per million man-hours worked. (By contrast, the fatality frequency for Ontario Hydro linemen, an occupational group that is also involved in an inherently dangerous work activity, was 0.49 for the same four year period.[19])

Several explanations have been put forward in an attempt to determine why the risk of death among demolition workers is so high. These explanations include the following: a) most demolition workers are paid on a per diem basis and are non-unionized (other sectors of the construction industry must draw employees from union halls), b) the demolition industry in Ontario is composed of two large companies and many small operations (some of which do not have expertise in demolition), and c) it is inherently more dangerous to tear down a structure than it is to construct one (e.g. because of hidden hazards).

The Research Branch of the Ministry of Labour has provided council with more recent data on the 10 Schedule 1 rate groups exhibiting the highest fatality frequencies in 1980.[20] This information is summarized in Table 1 (page 19).

It is clear that a mechanism for the routine, periodic review of fatality frequency and accident frequency statistics would assist greatly in identifying the classes of workers who are subject to particularly high levels of risk. This view, it should be noted, is shared by the authors of *The Report of The Joint Federal-Provincial Inquiry Commission into Safety in Mines and Mining Plants in Ontario*.[21]

Once a rate group exhibiting a high accident or fatality frequency has been identified, it is necessary to classify and analyse the types of accidents that are typically responsible for traumatic injuries within this group. The analysis should be directed towards the determination of cause and should seek to answer the following questions:

a) What was the condition of the working environment when the accident occurred (e.g. was there adequate lighting, were machine guards in place)?
b) What work practice was associated with the accident?
c) What was the level of training, direction and supervision in the workplace where the mishap occurred?
d) What sequence of events led up to the accident?
e) What steps could be taken to minimize the possiblity that a similar type of accident will occur in the future?

In the long run, the development of comprehensive frameworks for the screening and investigation of traumatic injuries in the workplace should contribute dramatically to the reduction of accidents, which, as has been indicated, is the leading cause of death among young Canadians.

Table 1

Fatality Frequency Data for the 10 Schedule 1 Rate Groups Exhibiting the Highest Number of Fatalities per Million Man-hours Worked

Rate Group Number	*Description of Economic Activity*	*Fatality Frequency Per Million Man-hours Worked*
106	(cross-cutting, drifting or shaft-sinking in/for mines as a business)	4.16
212	(ship-building or ship-repairing; operation of dry docks)	2.32
859	(business of supplying labour for wrecking of buildings; wrecking of buildings by a general contractor or as a business (i.e. demolition)	1.78
084	(mining of uranium-reduction, smelting and treatment)	1.61
054	(manufacture of such items as refrigerators, washing machines, wooden barrels, toys, turned and shaped goods, spokes and hubs for wooden vehicles, etc., not included in other categories)	1.02
076	(mining of nickel or nickel-copper, mining, reduction, smelting and treatment)	0.79
674	(operation of airplanes, airships or other flying machines)	0.65
001	(lumbering, logging, cord wood cutting woods operations, including construction and repair of dams, camps and the building of roads, along with other activities associated with the logging industry or with forestry contractors)	0.61
744	(manufacture of asphalt and paving materials; construction of sidewalks, etc.)	0.61
873	(caulking, decorating, glazing or installation of glass-plates; insulating, painting, steep-jack work, weather stripping, etc.)	0.47

The Potential Impact of New Knowledge and Advanced Technology on Occupational Exposure to Health Hazards

Just as there have been improvements in the knowledge base with respect to causation of occupational accidents and diseases, more sophisticated knowledge and technology have been applied to the processes involved in industry making it easier to reduce risks and exposure to hazardous substances. Because of the potential impact of this technology in reducing accidents and adverse health effects, it is useful to consider current changes as well as what may take place in the future. It is also important to recognize that the application of this technology may produce changes in the labour market, including the educational and/or training mix in the demand for labour, and will have implications for the preparation of people for work and in the area of retraining. The skill with which organizations apply new knowledge and technology and adapt to changing demands can be expected to have a marked effect on the progress to be made towards improvements in areas of occupational health and safety in the '80s.

On the one hand, there are pressures to introduce automation, remote control and robotic manufacturing at an increasing rate—aims being to improve productivity and product quality and to reduce occupational accidents and diseases. On the other hand, these changes can, potentially, have significant effects both on the labour market and on the thrust for occupational health and safety improvements, and particularly so in an extended period of high unemployment.

There are notable examples in the construction industry where, through the use of integrated materials handling systems, accidents have been markedly reduced at the same time as productivity and profitability have increased. In other sectors, a number of industries are moving to apply sophisticated engineering controls to reduce worker exposure to hazardous substances. For more than 10 years, Canadian technological capability has been recognized in the development of remote control space arms and, with a growing emphasis on engineering means for controlling worker exposure to hazardous substances, one can anticipate a trend to other remote control areas.

Remote manipulator systems are being developed for special applications in hostile environments so that worker exposure to radioactivity or extreme heat, for example, can be avoided. One potential application, for which feasibility studies are being undertaken, involves the use of manipulators to replace ceramic tiles cladding metal melting furnaces. This new technology would permit the replacement of these tiles without the attendant problems involved in furnace shutdowns.

The nuclear industry is another area where remote manipulating devices (for example in hot cells) are being used more extensively to reduce worker exposure. In situations requiring the handling of large radioactive sources, the use of remote systems significantly reduces the time which skilled staff must spend in the vicinity of high radiation fields. A combination of methods are employed to achieve radiation dose reduction, including, for example, reduction of the radiation field at source, remote handling, mock-ups and training, and design reviews.

The chemical industry is another field in which a rapid shift can be seen toward reducing exposure to health hazards. The capacity to detect and measure minute quantities of many potentially hazardous substances has increased in recent years to the extent that the sensitivity of analysis in some cases, such as for chromium, has increased to parts per billion and dioxin to parts per trillion. As the capability to produce extremely sophisticated sensing systems and control systems is developed and a more comprehensive view of environmental interactions is developing in the field of toxicology, the trend to reduced exposures can be expected to continue.

In the asbestos industry, the use of point control, in which every dust-emitting unit is enclosed and/or equipped with aspirators, has permitted emissions of asbestos fibres in existing plants to be controlled to an average of less than 2 fibres/cm^3 of air. Garlock of Canada, for example, an Ontario manufacturer of braided asbestos packing and compressed asbestos gasket sheet, using techniques including encapsulation, air control, and scrubber systems, has managed to control airborne asbestos fibre to the extent that at the time of this writing, the latest readings indicated levels of 1/3 fibre/cm^3 of air.[22] At the same time, the industry is working to devise means of controlling exposure to asbestos fibre in all phases of production and handling, including the transportation of fibre and asbestos products and the development of equipment and work practices appropriate for constructors.

As our understanding of the effects of hazardous substances on health increases and the technological capability to control hazardous substances develops, one can expect that reduction of worker exposure to such substances will continue and that new plants, from the outset, will incorporate the necessary design features to minimize risk to members of the work force. The nuclear industry is an example of an industry developed in the last 15 years in a high technology field involving a hazardous substance and where the plant and operation are designed to minimize risk to the worker. While this is an iterative process, costs involved are built into the cost structure of power generated.

It can be anticipated that, with proper incentives, new knowledge and technology will be increasingly applied in old and new workplaces as a means of reducing hazards to workers and of improving the quality of working life. This leads one to ask whether, with these developments, we will be moving towards a situation where there is virtually no exposure of workers to hazardous agents by the end of this decade.

Joint Responsibility

Avoiding the risk of undesirable trade-offs which may well threaten the momentum of occupational health and safety progress will be no easy task. The success of management, labour, and government in the undertaking of joint participation for the achievement of healthy and safe working conditions will depend, in large measure, on the ability of many organizations to adapt to the changing and intertwined array of demands facing them.

In facing changing demands, it is important that the collectivity of responsibility for health and safety and the changing needs and expectations of society are recognized. To effectively meet this challenge, it is appropriate that the means used take into account the intricate mosaic which exists in society and which includes a vast heterogeneity in people's facility to comprehend. The interactive association between health and socio-economic conditions[23] and the extent to which patterns of inequalities in health correspond to socio-economic patterns, suggests, as well, the need to more consciously consider these relationships in addressing health and safety matters.

Footnotes

1. Advisory Council on Occupational Health and Occupational Safety, First Annual Report, April 1, 1978 to March 31, 1979, Introduction. On this topic, see generally Sir Douglas Black, Inequalities in Health, Report of a Research Working Group, OHSS (London, England: Secretary of State for Social Services, August 1980) and Thomas McKeown, The Modern Rise of Population (London, England, 1976), and The Role of Medicine (London, England,1977).
2. Statistics Canada, Vital Statistics, vol. III, Mortality, Summary List of Causes, 1978 (Government of Canada, 1980) pp. 12-13.
3. M. Lalonde, A New Perspective on the Health of Canadians, A Working Document (Ottawa: Government of Canada, 1974), p. 15. Years of potential lost life were measured against a life expectancy of 70 years. Causes of infant mortality were excluded from the calculation.
4. *Ibid.*, p. 15.
5. R. Doll and J. Petro, 'The Causes of Cancer: Quantitative Estimates of Avoidable Risks of Cancer in the United States Today', in Journal of the National Cancer Institute, vol. 66, no. 6, 1981, p. 1205.
6. *Ibid.*, p. 1256.
7. *Ibid.*, p. 1241.
8. *Ibid.*, p. 1241.
9. Conversation with Dr. A. B. Miller, University of Toronto, February 1982.
10. The estimate of the number of deaths attributable to occupational exposures may be somewhat high, however, in that the figure of total cancer deaths includes skin cancers, most of which are not likely to be occupationally induced.
11. These figures represent cancer cases allowed for compensation and medical aid only claims, as calculated by Dr. D. Burton of the Ontario Workmen's Compensation Board. The information was supplied by the Research Branch of the Ministry of Labour.
12. As an example, vinyl chloride exposure levels of 0.5 parts per million (ppm) or lower have been achieved in Swedish chemical plants, see B. Holmberg and A. Westlin, 'Considerations in the Decision of the Swedish Occupational Health Standard for VCM', in C. Hammond and I. Selikoff eds., Annals of the New York Academy of Sciences, vol. 329, 1979, p. 204.
13. Advisory Council on Occupational Health and Occupational Safety, Fourth Annual Report, Appendix B.
14. World Health Organization, World Health Statistics Annual, 1978 (WHO: Geneva, 1978) III. 2.2, pp. 613-626.

15. Advisory Council on Occupational Health and Occupational Safety, Third Annual Report, April 1, 1980 to March 31, 1981, Support Document for Advisory Memorandum 80-II, Prepared by Professor R. D. Fraser, p. 83.
16. N. Knox and R. Eicher, Mort User's Manual, United States Energy Research and Development Administration, Division of Safety, Standards and Compliance, November 1976.
17. Advisory Council on Occupational Health and Occupational Safety, Third Annual Report, April 1, 1980 to March 31, 1981, Advisory Memorandum 80-IV, p. 162.
18. Correspondence from the Construction Safety Association of Ontario, January 1982.
19. Conversation with an official from Ontario Hydro, March 1982. Data on the actual number of man-hours worked by linemen during this period were unavailable. Instead, the man-hour component of the fatality frequency statistic was arrived at by multiplying the number of linemen in the employ of Ontario Hydro by 2,000—the usual number of hours worked per year.
20. Ontario Ministry of Labour, Research Branch, March 1982. The man-hour component for these statistics was derived from the Workmen's Compensation Board's assessable payroll, as reported by Schedule 1 employers . . . workers in individual rate groups may come under the jurisdiction of one safety association, several safety associations or not be covered by any associatons.
21. The Report of The Joint Federal-Provincial Inquiry Commission into Safety in Mines and Mining Plants in Ontario, Towards Safe Production, April 1981, volume 1, p. 156.
22. Conversation with an official from Garlock of Canada, March 1982.
23. On this topic generally, see Sir Douglas Black, *op. cit.* and R. D. Fraser, *op. cit.*

COUNCIL'S ADVISORY MEMORANDA

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April 27, 1981

J. F. Mustard, M.D.
Chairman
Advisory Council OHOS
15th Floor
400 University Avenue
Toronto, Ontario

Dear Dr. Mustard:

I am pleased to forward the lead regulation to the Advisory Council for review. I believe the Ministry has proceeded with the development of this regulation in an open manner and has encouraged the fullest participation of interested parties.

As you and your Council members are aware, on June 28, 1980, the Ministry issued a notice of intent through the Ontario Gazette to regulate lead as a designated substance. On August 16, 1980, the Ministry published the proposed lead regulation in the Ontario Gazette. In both cases, the Ministry placed advertisements in newspapers throughout the province to alert interested parties to the pending regulation. The Ministry also mailed copies of the proposed regulation to some people who we knew had expressed an interest in this regulation.

I would note that the Ministry had a minimum period of 60 days before which it could proceed with making the regulation law. Due to many requests for more time to comment, the Ministry extended the deadline to November 28, 1980. During this time, the Ministry had available, at its Library and District Offices, an interim report on lead which contained the rationale for the regulation.

In recognition of the quality of the briefs received, it became apparent that it might be helpful to all parties for the Ministry of Labour to share its analysis and reaction to the comments with those who had submitted briefs. A meeting was held with these individuals on March 25, 1981, to present the revised lead regulation. The Ministry has received some 19 additional briefs since this meeting and the Ministry's analysis is contained in the attached report on lead. This report also

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provides the Council with the detailed analysis of the earlier submissions and our reaction to the comments.

At the March meeting, the United Steelworkers of America requested, and the Ministry agreed to, a further meeting with their technical advisor(s) to review the rationale for the exposure limits. That review is now being arranged. Other parties have also requested meetings which are being scheduled at the earliest mutually convenient opportunity.

The meetings could possibly result in modifications to the attached regulation. If changes are made, the Ministry will forward copies to you for your consideration. However, since the Advisory Council is concerned with the process of reaching the final regulation, I believe that it is proper for me to forward, without further delay, a copy of the lead regulation for your review and comment on the process used by the Ministry in developing the regulation.

I look forward to receiving the advice of Council.

Yours truly,

Robert G. Elgie
Minister

Enclosures

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July 9 , 1981.

The Hon. Robert G. Elgie, M.D.
Minister of Labour
400 University Ave., 14th Floor
Toronto, Ont.
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Dear Dr. Elgie:

On behalf of the Advisory Council, I am enclosing Advisory Memorandum 81-I in which Council has reviewed the process for the development of the lead regulation, in light of the policies and principles set out in Advisory Memorandum 78-II.

I remain,

Yours truly

J.F. Mustard, M.D.
Chairman

Attach. 2

cc: Mr. T.E. Armstrong
Dr. Ann E. Robinson

Advisory Memorandum 81-I
to the Minister of Labour
July 9, 1981

A Review by the Advisory Council of the Process used to Develop a Standard for Lead and Council's Evaluation of the Criteria utilized to Assess the Hazard of Lead Exposure in the Workplace.

INTRODUCTION

In February 1978, the advisory council and the then Minister of Labour agreed that council should be given the task of reviewing the principles and procedures used in setting occupational health standards and guidelines in Ontario. In Advisory Memorandum 78-II, council set out a list of the basic principles and procedures that should ideally characterize the policy process in respect to establishing standards, guidelines and codes. In this document, council undertook to review the criteria utilized by the Ministry of Labour in evaluating occupational health hazards and to follow the ministry's standard setting process through to its final form. It was also clearly understood that council would limit its review to the process leading to the development of ministry standards. In its memorandum, council also stated that it would require 30 days to complete its review function. In subsequent correspondence with the minister, it was agreed that, because of public interest in the area, council's review of the standard setting process should be submitted in the form of an advisory memorandum.

In June 1980, the Ministry of Labour published a Notice of Intent to designate lead as a substance 'to which the exposure of a worker is prohibited, regulated, restricted, limited or controlled under the *Occupational Health and Safety Act.*' This was followed, in August 1980, by a notice setting forth the ministry's proposed regulation for lead. The notice invited public comments and stated that such comments would be made available for public examination. At the same time, the ministry distributed copies of the proposed regulation and three accompanying codes to interested members of the public. In October 1980, the ministry distributed a document entitled *Interim Report on the Designation of Lead in Ontario*. This document dealt with such topics as the use of lead in Ontario, workplace exposures to lead, the control of occupational lead exposure and the health effects produced by exposure to lead. Each interim report also contained a copy of the proposed regulation and codes. On March 25, 1981, the ministry held a public meeting to discuss changes that had been made to the August 1980 version of the regulation. A revised version of the proposed regulation and accompanying codes were distributed at this time, along with an entirely new Code for Medical Surveillance for Lead. Invitees were told that they would have a short period of time to comment on any revisions that had been made to the regulation and codes.

On April 27, 1981, the Minister of Labour submitted to council a revised version of the lead regulation, subject to any amendments that might be made as a result of submissions made after the March 25 public meeting. Included with the regulation was a document entitled *The Report on the Designation of Lead in Ontario*. This document contained, among other things, a summary of the views expressed by members of the public on the various provisions contained in the first and second drafts of the regulation. The type of action taken by the ministry in response to the submissions made was also outlined. Annexed to the report was a further document entitled *Assessing the Impact of Designated Substances Regulations*. This document dealt with several topics, including the type of economic impact that Ontario industry would likely experience if the provisions contained in the lead regulation were implemented.

In response to the minister's letter, council stated that it would submit its advice in two stages. Since all the provisions contained in the regulation were not yet finalized, council felt that it would be inappropriate to comment on the 'analytical' and 'legal-technical' aspects of the standard setting process until such time as a final, definitive version of the regulation was received. Council concluded, however, that it would be proper to comment on the 'consultative process' undertaken by the ministry in the development of the lead standard. These comments, along with some initial concerns that council had in respect to the analytical and legal-technical aspects of the standard setting process, were transmitted to the minister in a letter dated May 15, 1981. The contents of this letter appear as Appendix 1 to this report.

On June 3, 1981, the minister replied to council's letter and noted that, as a result of the questions raised by council and by others, some additional changes had been made to the regulation and codes. The ministry also supplied council with a six-page reply to the concerns outlined in council's letter of May 15. The minister's letter also contained a copy of the final revised version of the lead regulation, dated June 3, 1981. The minister's letter, as well as the accompanying explanatory material, may be found in Appendix 2.

COUNCIL'S REVIEW OF THE STANDARD SETTING PROCESS FOR LEAD

To reiterate the comments made in our letter dated May 15, 1981, council wishes to commend the ministry for the steps it has taken to make possible public participation in the consultative process surrounding the development of the lead regulation. Council strongly endorses the ministry's efforts to develop an open process for the setting of standards. Council feels that the following extra steps might enhance, even further, the quality of the consultative process:

1) The ministry should provide, where possible, a clear statement of the criteria utilized to set control levels for particular designated substances (e.g. the method employed to determine the significance of a health related effect produced by exposure to a designated substance and the principles that are used to draw inferences from data that are incomplete or otherwise inadequate, etc.).

2) A statement of risk assessment should be included in the ministry's background material. (Such a statement should provide an estimate of the percentage of workers likely to be protected from the health effects associated with a particular designated substance at specific control levels).

3) The ministry should provide, at an early stage in the regulatory process, background material for Ontario, classified by different industries, on:

   a) the results of biological monitoring for workers in the province who are occupationally exposed to particular designated substances, and

   b) the airborne and biological levels currently being achieved in respect to these substances by the identified industries.

4) The economic impact assessment produced by the ministry as part of its general process of risk assessment should be made available to interested parties at an early stage of the standard setting process.

5) All codes that are referentially incorporated into a designated substances regulation[1] should be distributed with the first draft of the regulation in order to maximize public input.

6) In organizing public meetings to discuss draft versions of designated substances regulations, it would be best if the ministry could distribute relevant materials to participants before the actual dates of the meetings.

The use of the public meeting as an integral part of the standard setting process is obviously constructive. In its letter of May 15, council has already expressed its views on this subject. Because of the important role that such meetings play in the development of regulatory policy, council will provide further comment, at a subsequent date, on the manner in which public meetings could be structured to produce a maximum impact on the overall process of setting standards.

In assessing the manner in which the ministry has conducted an analysis of the relevant information used to develop the lead regulation, council faces a difficult task. In essence, council must judge how effectively the ministry has assembled and presented the evidence for use in the decision making process. As stated in Advisory Memorandum 78-II, council is clearly not the body to make a judgement as to what these levels should be. However, council has the responsibility of commenting on the soundness of the analytical process used by the ministry in arriving at its recommended levels. Council intends to discharge this role as objectively as possible.

In embarking on this task, council has the advantage of examining a complex and difficult process in its final stage. Hence, council is in a position to review not only the arguments put forward by participants, but also the rationale supplied by the ministry for formulating its regulation in a particular fashion in light of the evidence and arguments raised.

It is evident that the ministry has considered both the scientific evidence relating to the health effects of lead exposure and the different views expressed by members of the public in establishing its policies. Council has a number of concerns, however, that touch on the analytical process utilized by the ministry to arrive at the control levels specified in the regulation.

On the basis of the background material provided by the ministry, and in view of the briefs submitted by members of the public, council believes, as stated earlier in this memorandum, that it would have been better had the ministry set out a more detailed form of risk assessment, indicating how it arrived at the control levels for exposure to lead that are found in the regulation. Ideally, the ministry ought to have provided data, at an early stage in the standard setting process, on the percentage of workers who would likely suffer specific lead related health effects at particular air lead and blood lead levels. Council believes that information of this nature should be supplied, whenever possible, in the form of dose-effect curves based on published studies. In the context of regulating exposure to lead, for example, it would have been useful had the ministry set out dose-effect curves for separate lead-related health effects (e.g. interference with blood synthesis and damage to the neurological, reproductive and renal systems). The individual curves could then be assessed to help evaluate the health benefits and risks that would accrue from setting exposure limits at various levels. Information of this sort would have greatly facilitated the exchange of views among all interested parties.

The ministry's background material clearly indicates that there is reasonably good evidence to suggest that biological effects occur in humans at blood lead levels below 0.70 mg/L. Some uncertainty exists, however, on the subject of whether such effects are biologically significant. In selecting a blood lead removal level of 0.70 mg/L for men, and for women not capable of bearing children, the ministry is presumably of the opinion that if workers are removed at this level, blood lead levels will fall, and injury to tissues in the body will not occur.

However, in the face of similar concerns about health effects on the fetus, the ministry has adopted a lower blood lead removal level (0.40mg/L) for women capable of bearing children. It would appear that this decision was based, in part, upon animal experiments, which indicate that low levels of lead exposure can produce damage to the neurological systems of animal fetuses.

The decision to set one blood lead removal level for women capable of bearing children and another level for men and all other women, raises two concerns. First, it would have been preferable had the background material supplied by the ministry contained a discussion to suggest why a lower blood lead removal level should not be adopted for all workers exposed to lead. Second, in setting a different control level for a selected group of workers at a late stage in the regulatory process, there is the risk that some points (e.g. issues involving human rights and employment opportunities, and the question of whether children born with birth defects caused by exposure to toxic agents should receive compensation) may not have been adequately debated. In the general process of developing its regulations, the ministry must balance the benefits to be gained from additional public input against the desirability of promulgating a standard in an expeditious manner.

In council's view, the ministry, by adopting a 0.70 mg/L blood lead removal level for all males and for females not capable of bearing children, has accepted the principle that the lead regulation should be generally geared towards the control of detectable clinical effects rather than towards the control of more subtle biological effects. Since it is known that low levels of lead exposure can affect a number of biological systems in humans (i.e. the blood forming, neurological, renal and reproductive systems), the relatively high blood lead removal level set forth in the regulation could subject some workers to potential health risks, the extent of which are not entirely understood. An alternative approach would involve setting lower control levels to minimize potential risks to workers.

In this regard, council wishes to emphasize that biological monitoring of workers exposed to lead should not be regarded as a substitute for the introduction of adequate control measures in the workplace.

In its letter to the minister dated May 15, 1981, council made reference to the complexities that characterize the relationship between air lead levels and blood lead levels. Since there is uncertainty in respect to (a) the health effects that could develop at blood lead levels below 0.70 mg/L and (b) the exact relationship between air lead and blood lead levels, it is clear that some uncertainty must also exist in respect to the 0.15 mg/m^3 airborne level for inorganic lead specified in the regulation.

Obviously, in arriving at the decision to set a standard at a particular level, one is faced with the cost of control. In the background material provided to council, the ministry concludes that the 0.70 mg/L blood lead removal level will not generate significant new costs for industry. A key question that has not been answered, however, is whether a lower level could be achieved without imposing significant additional economic costs. In this regard, council has concerns about the apparent lack of integration of economic analysis in the process of developing the lead regulation. In the absence of a comprehensive economic assessment detailing the costs that would likely result from different levels of control, council is left with the impression that it might have been possible to further reduce the risk to workers at relatively little cost to industry. Without the appropriate background material, however, council cannot reach a conclusion on this issue.

It is clear that uncertainty exists about the desirable levels of control for occupational exposure to lead. In this regard, the ministry has expressed its own concerns about the relationship between exposure to low levels of lead and health effects.

> 'Some recent research suggests that chronic impairment of various kinds (neurological, psychological, renal) occurs in workers whose blood lead level according to exposure records never exceeded 0.70 mg/L. This type of research is receiving particularly careful attention. If the assumption that blood lead levels never exceeded 0.70 mg/L can be substantiated, it will be necessary to reconsider the proposal to use 0.70 mg/L as the level for mandatory removal from exposure. This would imply that the time-weighted average of lead in air should be controlled at something below 0.15 mg/m^3. In view of this possibility, it might be prudent to indicate to industry the importance of working toward lower workplace concentrations in the future.'

As has already been stated, it is not the role of the advisory council to recommend levels of control for designated substances. The following comments should not, therefore, be interpreted as an attempt by council to set levels. However, in view of the uncertainties delineated in this advisory memorandum, council wonders whether this uncertainty should not have been taken into account in framing the lead regulation and accompanying codes. In this regard, council suggests that, as an initial step, the ministry gives consideration to lowering the 0.60 mg/L action level for 'enquiries regarding work practices and personal hygiene', found in section 4(1) (a) (i) of the Code for Medical Surveillance for Lead. In addition, because of the changing knowledge base in this field, council strongly urges the ministry to frequently review the control levels specified in the regulation and codes, and to make appropriate changes as more knowledge is gained about desirable levels of control.

In view of the importance of this issue, council intends to produce a further advisory memorandum on the principles and procedures that could be utilized to address the uncertainties that characterize the choice of appropriate control levels for designated substances. Council's task force on health surveillance and health screening is currently examining the relationship between environmental monitoring and biological monitoring, an issue that bears on this general area of concern.

In its final review, council has several uncertainties that relate to the analytical and legal-technical aspects of the standard setting process for lead. The uncertainties may be summarized as follows:

1) the question of whether a ministry inspector has the authority to order an employer to conduct a workplace assessment when the employer claims that the regulation does not apply to his workplace,
2) the need to define precisely the meaning of the terms hygiene practices, work practices and engineering controls as they appear in section 4 of the regulation, and the advisability of the phraseology found in section 1 of the Code for Medical Surveillance for Lead,
3) the question of whether the Code for Medical Surveillance for Lead should provide that two blood lead tests indicating that a worker's blood lead level has fallen to 0.50 mg/L or below (as opposed to the one test currently specified in the code) should be required before a worker, who has been removed from a work site because of exposure to lead, may be permitted to return to work, and
4) the question of whether a formal scheme of rate retention, over and above workmen's compensation, should be implemented to protect workers who have been removed from work because of exposure to lead, and the issue of whether Ontario industries could bear the costs associated with such a scheme.

In council's review of the process used to develop the lead regulation, a number of issues have been raised. It is council's intention to address some of these issues in future deliberations. In addition to the points discussed above, council will give consideration to the following topics: the issue of access to medical information; the question of whether medical testing should be made mandatory or voluntary; the application of economic assessments to the occupational health field; the need for each designated substance regulation to contain a statement of purpose; the desirability of action levels, and the question of how small business can be encouraged to participate more fully in the process of standard setting.

CONCLUSION

Any process for developing a regulation to control a health hazard is bound to have difficulties. When the process is open, an agency charged with the performance of this task must exercise considerable skill in arriving at a reasonable conclusion.

In this initial attempt to develop a designated substances regulation within the context of an open consultative process, all groups (including labour, management, the ministry and the advisory council) have participated in a complicated learning process. In this regard, the contributions made by each of these groups may not have been as effective as they could have been. Notwithstanding these difficulties, it is clear that the consultative process adopted by the ministry has greatly facilitated the exchange of ideas and information. Furthermore, input from labour, management and other groups has caused significant improvements to be made to the August 1980 draft version of the regulation.

Although all participants may not be satisfied with the alterations that have been made, the advisory council must commend the ministry for conducting an open standard setting process. Council also recognizes that, with experience, all parties will be better able to contribute to the consultative process so as to maximize the quality of regulations developed for the control of hazardous agents in Ontario workplaces.

Footnotes

1. It is council's understanding that the ministry believes that the codes that have been incorporated by reference into the regulation are legally binding documents in their entirety.
2. Ontario Ministry of Labour, Occupational Health and Safety Division, Special Studies and Services Branch, 'Health Effects of Lead', in *The Report on the Designation of Lead in Ontario*, Appendix H, (Toronto, 1981) p.H-13.

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APPENDIX 1

May 15, 1981

The Hon. Robert G. Elgie, M.D.
Minister of Labour
400 University Avenue
14th Floor
Toronto, Ont.
M7A 1T7

Dear Dr. Elgie:

Thank you for forwarding to us the lead regulation and the background material associated with it. We appreciate the opportunity to begin our review and response before the final regulation is available. We would also like to have members of the Heard task force meet with your officials to clarify some of the points discussed below.

Since we have not seen the final regulation, we will submit our response to you in two stages. Initially, we will comment on the consultative process that has been undertaken in developing the regulation. We will also, in thisfirst stage, indicate a number of analytic issues which we have identified in our review of the regulation and the associated background material. In addition, there are a number of legal/technical problems which appear to have arisen out of the drafting of the regulation and the accompanying codes. It is hoped that, either before or with the final regulation, your ministry will be able to provide us with additional information with respect to these matters. In a second stage, after receiving the final regulation and this additional background material, we will wish to comment more fully on these analytic and legal/technical aspects of the process.

In Advisory Memorandum 78-II council set out a list of principles and procedures that should ideally characterize the process of developing regulations. We will structure our comments on the particular process of developing the lead regulation in light of the recommendations contained in that advisory memorandum. The overall guiding principle that underlay those suggestions was a need to ensure a process as open and comprehensive as possible in introducing all relevant information and allowing for the expression of the various affected interests.

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Council's general assessment of the process that has been undertaken over the past few months is that it has indeed satisfactorily addressed this overriding concern. In fact, the process has, if anything, been more open than was originally envisaged. There are, however, several particular suggestions that council has with respect to refining and, perhaps, streamlining the consultative process in development of other regulations for designated substances.

Council realizes that, in addition to this process being the first of its kind, it has a unique feature in that the Notice of Intention to designate lead, which was gazetted in June, 1980 under the provisions of the Occupational Health and Safety Act, 1978, had been preceded in July 1978 by the gazetting of an earlier Notice of Intention and proposed regulation, under different legislation. Council appreciates that the publication of a Notice of Intention and of a proposed regulation in 1978 may, in this case, have made it unnecessary to produce a Statement of Intent and Proposed Action in association with the Notice of Intention of June, 1980. Council would like to reiterate, however, that it believes that a Statement of Intent does constitute an important initial activity in the general process of developing regulations. It is Council's view that a Statement of Intent to regulate should include background material on the prevalence of potential hazardous exposure to the substance in question within Ontario, based on whatever data have been collected both in the field and within the ministry, and furthermore, should set the intent to regulate in the context of a statement of general principles and policies concerning the development of regulations for hazardous substances. In particular, there should be a statement of the risks and costs related to different standards, and an indication of the criteria used to specify the level of risk that is to exist at the workplace. Council expects that in future cases there will be provided, with the Notice of Intention, a Statement of Intent which deals with all these issues.

Council is also concerned about the timing of certain aspects of the consultative process. For example, the Interim Report on the Designation of Lead in Ontario was not publicly available until October 1980, though the proposed regulation was published in August of that year. The economic analysis section was not available in the Interim Report and, indeed, was not even available by March 25, 1981 when the meeting with interested parties occurred. In future, it would be hoped that such reports would be made available with the draft regulation. It should also be noted that, though the codes now constitute important elements in the regulation of lead in Ontario, they were not all available for review and comment by interested parties even as late as March 25, 1981. A fifth code, the Lead Code of Practice, is still not available. Since parts of the regulation were transferred to the codes, council believes that it is important in the future process that the codes be made available at the same time as the draft regulation.

...3

Council believes that the delays, and the fact that this is the first regulation, may have impeded the ability of some respondents to develop reactions to the proposed regulation and background material in as comprehensive a manner as they might have done. In addition, council is concerned about the entire length of time it has taken to get to this penultimate stage of developing the lead regulation. This, no doubt, reflects the inherent difficulties of undertaking a new process and council is aware that, with this experience, the ministry will be in a position to expedite the development of future regulations.

Council would also like to comment on the insertion of the March 25th meeting into the consultative process. While we appreciate the desire of the ministry to be as open as possible in the process of developing regulations, and acknowledge the usefulness of a public forum in promoting that openness, we are concerned about the insertion of this additional stage for several reasons. First, it should not unduly lengthen the entire process. Second, in the future, the existence of such a stage in the consultative process should be made clear at the beginning so that parties can plan their work accordingly. Third, such a meeting should be truly public and notice of its occurrence should be advertised, with attendance available to all interested parties, and not only to those who have submitted briefs in earlier stages of the process. Finally, to facilitate a useful interaction at what is necessarily a time-constrained meeting, written material should be made available to parties who have submitted earlier briefs, in advance of the public meeting, containing discussion of the ministry's response to comments received and anticipated revisions to the proposed regulation.

With the addition of the above administrative changes, council endorses the inclusion of a public forum in the process as a whole. We do believe, however, that such a forum should constitute the last stage in the consultative process. We would encourage you to consider the advisability of notifying the parties that such a public forum constitutes their final formal opportunity to have input into the regulating process.

Council recognizes that, with our form of government, interested parties may well make representations to government outside of the consultative process. Council does not believe that its review should take into consideration any informal, unsolicited parts of the process, as they are the responsibility of the minister and the government. For example, we would consider your recent meetings with the organizations referred to in your letter as not being part of the formal consultative process and, therefore, not subject to our scrutiny. If such advocacy leads to major changes, the arguments will, presumably, be made public and the changes explained by the government in association with its final regulation.

Council hopes that these suggestions can be used to improve the process. Council appreciates the substantial efforts that have been made by the ministry in undertaking a new and difficult

....4

consultative process and believes that what has been achieved represents an important improvement in the way regulations are developed in this province. Council therefore endorses, with the concerns noted above, the general process that has been carried out for the lead regulation.

In reviewing the regulations and the codes, together with the background material submitted to council on April 27, 1981, council identified a number of other issues that should be considered in relation to council's review of the suitability of the process in respect to the final regulation. These can be grouped under two broad headings: 1) the analytical process and, 2) the legal/technical part of the process, particularly as it relates to the drafting of the regulation and the codes.

It is important to emphasize that, in reviewing the issues under the first heading, council does not intend to pass judgment on the final values selected by government, but rather, it is concerned about whether the evidence appears to have been assembled, reviewed and analysed in a manner that is compatible with the final conclusions.

Some of our specific concerns are as follows: The reasons for selecting the standards do not appear to be fully stated in relation to the available evidence. The information provided does not appear to give adequate justification for how the level of .15 mg. lead per cubic meter of air was selected rather than a higher or lower level. In light of the debate on the possible benefits from establishing a lower exposure standard, it is not clear whether the economic feasibility of going to a lower level was actually considered. Council would appreciate clarification of these matters in order to be able to comment on whether the analytical process leading to the levels selected appears to be based on a reasonable interpretation of the available evidence.

Council is concerned about the changes which have been made in the regulation and codes in respect to blood lead levels. In making these changes, the linkage of the standards for airborne lead and for blood lead levels does not appear to have been adequately explored. The background material implies that one can have relative confidence in the higher standard of .15 mg. lead per cubic meter as long as there is mandatory removal of workers with elevated blood levels. However, our reading of the proposed regulation suggests that such removal is no longer mandatory and thus calls into question the argument advanced to support the airborne lead level contained in the regulation. Council would appreciate further discussion of the reasons for this change and of its implications, if any, for the justification of the airborne levels that have been put forth.

...5

Council would like further clarification of the analysis in respect to the question of whether employers should have access to the results of individual blood tests. This has been unclear to council in reading the material.

Council would appreciate further disclosure of the analysis done in the area of the economic impact on the worker of removal from lead exposure, and also further discussion of the reasons why the consequences of such removal were not dealt with in the regulation or the codes.

There are also a number of legal/technical issues related to the framing of the regulation and the codes.

Changes in the regulation between August 1980 and March 1981 leave it unclear as to whether physical examinations of workers are, or are not, mandatory. It would appear to council that the intent of the ministry is that the tests should not be mandatory, and that it is left to the individual employer to make them a condition of employment, if he so wishes. If this is the intent of the regulation, it should be made clear and reasons for this position should be articulated.

The access of workers to their exposure records appears to have been left in doubt in the regulation and the reasons for the decision to prohibit the authorization of agents have not been fully discussed.

There appears to be some doubt on the application of the regulation both in respect to workplaces where lead alloys are used and in terms of the relationship between the assessment under Section 6(1) and the judgment apparently required under Section 3(1) as to whether the regulation applies to an employer in a specific instance.

The relationship of the regulation to the codes, especially the Code for Medical Surveillance, needs to be clarified. For example, the Code for Medical Surveillance is referenced only in connection with medical procedures, but not in connection with guidelines for removal of a worker from exposure. Council notes that it has not yet seen the fifth code and expects that it will have it in association with the final regulation.

...6

These comments indicate some of council's concerns with analytic and technical aspects of the regulation, the codes and the background material. More particular, and perhaps less important items can be communicated to your officials in their meeting with the Heard task force. Furthermore, additional items may arise both in those meetings and in council's consideration of the final materials we receive. We hope, however, that this initial indication of our areas of concern will be helpful to you in this final stage of preparing the lead regulation.

Yours truly

J.F. Mustard, M.D.
Chairman

cc: Mr. T.E. Armstrong

Dr. A.E. Robinson

Office of the Minister

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APPENDIX 2

June 3rd, 1981

Dr. J. Fraser Mustard
Chairman, Advisory Committee on
Occupational Health and
Occupational Safety
15th Floor,
400 University Avenue,
Toronto, Ontario
M7A 1T7

Dear Dr. Mustard:

I write to thank you for your letter of May 15th, 1981 concerning the lead regulation. I appreciate the effort members of the Council have devoted to the analysis of the consultative process, the analytic process and the technical/legal process.

I am pleased to note the Council has endorsed with minor reservations the consultative process used by the Ministry in developing the regulation. Ministry officials would be pleased to discuss your comments on the issues of notice, timing, publication of background information and the holding of public meetings.

I believe it is incumbent on the Ministry to share its analysis of and reaction to briefs submitted on a particular proposed regulation. This provides interested individuals with an additional opportunity to comment and provides me the additional information necessary for carrying the regulation to completion. While this may entail a longer development period for a regulation, it may well serve to shorten the ultimate time it takes to file a regulation.

You have raised several important questions concerning:-

- the ministry's analysis of evidence supporting the proposed exposure limit of 0.15 mg of lead per cubic metre of air and 0.70 mg of lead per litre of blood.
- mandatory removal of workers with blood lead levels in excess of 0.70 mg/m^3.

..../2

- employer access to blood lead results.
- whether medical examinations are mandatory.
- the legal status of the codes referenced in the regulations.
- the reason for "authorized agent" being removed.
- whether lead alloys are included in the definition of lead.
- whether employees have redress in a dispute over the application of the regulation.

As a result of your questions and those raised by others since the March 25th meeting, some changes have been made to the regulation and codes. A final revised lead regulation is attached as is an analysis of your questions prepared by the Ministry. Dr. Robinson and her staff are prepared to discuss the reply with you at your earliest convenience.

Once again, I thank you for your conscientious effort.

Yours truly

R. G. Elgie
Minister

RGE:mw

Encl.

Lead Regulation
Revised June 2, 1981

Ministry of Labour — Reply to Analytical and Technical Issues Raised by the Advisory Council on Occupational Health and Occupational Safety.

1. *Rationale for exposure limit*

The exposure limits were selected on the basis of the known adverse health effects of lead, the blood level concentrations at which adverse effects on health become apparent and the ambient air concentrations that, with good personal hygiene practices on the part of workers, would not result in blood lead concentrations at which symptoms might be expected to become evident.

The health effects of lead in the background documentation provided to the Council (Appendix H) were considered under five body systems and it would appear that the most critical systems (those systems where effects are detectable at the lowest exposure levels) were and still are the hemopoietic and nervous systems.

Some recent literature suggests that biological effects on these systems (changes in enzymes associated with the hem-synthesis, small changes in the level of blood hemoglobin, a minimal decrease in nerve conduction velocity) may be detected in some workers who have blood lead concentration up to 0.7 mg/L, despite the fact that the workers in whom the changes are detected do not complain of symptoms. These workers should not experience a decrease in their health status, as the changes are reversible upon withdrawal from further exposure to lead.

The assumption that a time-weighted average of 0.15 mg of lead per cubic meter of air is unlikely to result in a blood lead level above 0.7mg/L is based on the work of Williams (1969) and is discussed on page 11 of Appendix H.

Thus, it is still valid to state that exposure to a time-weighted average of 0.15 mg of lead per cubic meter of air, for a worker who observes good hygienic practices, is unlikely to result in a blood lead level about 0.7 mg/L.

In the United States, the decision to attempt to lower the atmospheric lead exposure standard from 0.20 mg to 0.05 mg lead per cubic meter of air was based on the prevention of any detectable biochemical or physiological change assuming that any such change was the first stage in a disease process rather than a biochemical adaptation mechanism. This is not necessarily the case and the changes may represent only an adaptation mechanism on the part of the body to a change in its environment.

As the above analysis has indicated, a change in the exposure limit is not warranted at this time. However, because of the evidence of the sensitivity of the developing foetus to the adverse effects of lead, special provision has been made for limiting the blood lead levels of women capable of bearing children. For the latter group, the Code for Medical Surveillance will require that blood levels be maintained at, or below, 0.4 mg of lead per litre.

The exposure limit is based upon the Ministry's analysis of the scientific literature of the health effects of lead. The Ministry did not conduct an economic analysis of a lower exposure limit because the evidence on health effects did not lead to the conclusion that a lower limit was warranted at this time.

2. *Mandatory removal and wage protection*
   Sections 7, 13 and 16 govern the provisions of medical examinations and clinical tests. Under section 7, an employer is required to set up a lead control program which much include a medical surveillance. Section 13 sets out the general nature of the examinations and tests required, and adopts by reference the Code of Medical Surveillance for Lead.

   The code is a legally binding document. This code has been modified to ensure that a worker will be removed from exposure when his blood lead is in excess of 0.70 mg/m^3, or when a physician indicates to the employer that his health is impaired because of exposure to lead. Section 16 governs the advice and information which an employer may receive from a physician. A new subsection has been added which will ensure that employers and employees are aware of duties and rights with regard to compensation when a worker is removed from exposure.

3. *Mandatory Medical Examinations*
   Sections 7 and 13 of the April 6th revision of the lead regulation made it clear that the Ministry of Labour expected employers to provide a medical surveillance program for workers exposed to lead. However, the regulation was silent on whether workers were required to participate in the medical surveillance program and to take the tests set out in the Code for Medical Surveillance.

   In effect, the regulation permitted employers and employees to decide whether participation was mandatory or voluntary. In order to ensure consistent and uniform protection of workers' health, and taking into account section 17(1) (e) of *The Occupational Health and Safety Act*, section 13 of the regulation has been modified to require workers to undergo medical examinations and clinical tests required in a lead control program. It is the Ministry's intention through its routine audit of medical surveillance programs to work with employers and physicians so that workers are informed of the need for the tests and examinations and participate voluntarily instead of by compulsion. Where education fails, the Ministry and the employer require the additional authority to ensure that workers exposed to lead receive adequate surveillance and protection. Hence, the need to make medical examinations and clinical tests mandatory.

4. *Access to blood lead results*
   In August, the Ministry of Labour proposed that a worker's authorized agent should have access to the records of medical examinations and tests. This provision was removed from the April 6th version of the

regulation because the Ministry was concerned that workers could be harassed into authorizing employers to gain access to this information on a routine basis.

The phraseology, "authorized agent", was also questioned, in that some employers believed that a union representative could automatically be considered an authorized agent and would not obtain the informed consent of the worker to gain access to the medical records.

Due to these arguments, and because a worker has the right to provide this information to whomever he wishes, the regulation was amended as there was no necessity for a worker to authorize a third party to gain access to records of medical examinations and tests.

Since then, employers have argued that to protect their workers, they need direct access to the results of blood and urine lead tests. This request has not been acceded to because health and safety at work is a shared responsibility. It would not be fair to provide this information to the employer without at the same time ensuring that a worker representative(s) has (have) equal access.

Such an argument was advanced by the Royal Commission on the Confidentiality of Medical Records and the Ministry concurs with it. The Krever report recommended access to information by joint health and safety committees, but subject to a duty of confidentiality. This is reflected in the new wording in subsection 3 of section 16.

The Ministry believes this new provision is in keeping with the watchdog role of the joint health and safety committee and the need to strengthen its advisory role.

To this end, the Ministry has amended section 16 of the regulation to require the physician to provide the results of blood and urine tests to the joint health and safety committee. In order to ensure that the committee members understand these values, the Ministry will require a physician to provide his interpretative advice.

5. *Access to exposure records*
Subsections (a) and (b) of section 12 require records of a worker's exposure to lead to be posted in the workplace for at least fourteen days and furnished to the joint health and safety committee, or to the workers, or their representatives, who participate in an arrangement, plan or program.

To clarify a worker's right to access to this information, section 16 was changed to enable the worker to obtain a copy of his exposure record from the examining physician as well.

6. *Application of the Regulation*
The Advisory Council raised two questions concerning the application of the regulation. The first is a technical matter concerning lead alloys. Lead alloys are covered by the definition of lead provided in section 3 of the regulation.

The second question is more fundamental, in that the Council suggests that the combined effects of sections 3 and 6 of the regulation are circular, in that an employer could decide that the regulation does not apply to him since his workers would not be exposed to lead. Likely consequences of such a decision are: the employer would not conduct an assessment, and therefore, would not consult with his employees.

Under section 6, employers to whom the lead regulation applies must make an assessment and consult thereon with a joint health and safety committee or similar consultative group of workers. Section 3 sets out the basis for deciding whether the regulation applies. The basis may be determined in an objective manner, the tests being presence, use, handling, storing, etc. of lead and likely worker exposure.

While an employer may decide that the regulation does not apply, the Ministry and the workers have the right to rectify any mistaken judgement by an employer. Workers may complain to the Ministry who would investigate, and if it is found that lead is present and workers are likely to be exposed, the Ministry would order that an assessment be conducted. The Ministry will also exercise its investigative powers independent of any worker complaint. In either instance, failure to follow an inspector's order would place an employer in contravention of the Act with all the consequences which may follow from this position.

7. *Lead Code of Practices*

A draft copy of this explanatory material is attached. Unlike the Code for Respiratory Equipment, the Code for Measuring Airborne Lead, the Code for Medical Surveillance, and the Code for Determination of Lead in Blood and Urine, this explanatory material is not incorporated by reference in the lead regulation, and so lacks legal status.

The information in the report will assist employers and workers in exercising their duties and rights under the regulation. In order to prevent confusion with the legally binding codes referenced in the regulation, the Ministry has adopted another title for this information, "Working with Lead: Guidance Notes".

Office of the
Minister

Ministry of
Labour

400 University Avenue
Toronto Ontario
M7A 1T7

August 5, 1981

Dr. J. F. Mustard, Chairman
The Advisory Council on Occupational Health
and Occupational Safety
15th Floor
400 University Avenue
Toronto, Ontario
M7A 1T7

Dear Dr. Mustard:

I am pleased to be able to advise that on the 22nd day of July, 1981, His Honour the Lieutenant Governor in Council made a regulation with respect to lead under The Occupational Health and Safety Act, 1978.

The regulation will be filed with the Registrar of Regulations on the 14th day of August, 1981, and will therefore be enforceable as of that date. Copies of an office consolidation of the regulations and codes will be available to the public on the 17th day of August, 1981.

Attached for your information are three notices that have been prepared to cover the transmission of complimentary copies of the lead regulations to:

a) interested and affected parties;

b) those parties that participated in the deliberations with respect to the lead regulation, and

c) organizations which, according to our files, now use lead or have used lead in the past.

I would like you to thank the members of Council on my behalf for their valuable input into the development of the regulation.

Yours very truly,

Robert G. Elgie, M.D.
Minister

Attachments:

Ontario

Office of the
Minister

Ministry
of
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400 University Avenue
Toronto, Ontario
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August 11, 1981

Dr. J. Fraser Mustard,
Chairman,
Advisory Council on Occupational
  Health and Occupational Safety,
15th Floor,
400 University Avenue,
Toronto, Ontario
M7A 1T7

Dear Dr. Mustard:

Thank you for submitting the Advisory Council's Memorandum 81-I.

I am pleased to note that Council endorses the Ministry's efforts to develop an open process for establishing regulations for designated substances. I note the six additional steps which Advisory Council has proposed to enhance the effectiveness of the consultative process. These proposals can be summarized as follows:

(1) that the Ministry should provide, where possible, a clear statement of the criteria utilized to set limits for exposure to a particular designated substance;

(2) that a risk assessment should be one criterion of the statement;

(3) that, at an early stage in the regulatory process, the Ministry should provide background material for different industries within the Province relating to:

    (a) the results of biological monitoring tests of workers who are occupationally exposed to a particular designated substance, when such data are available; and

    (b) current values for airborne and biological monitoring data, if available, in respect of each substance, by the identified industries.

(4) that the economic impact assessment produced by the Ministry as part of its general process of risk assessment should be made available to interested parties at an early stage of the regulatory process;

(5) that all codes which are referenced or incorporated into a designated substance regulation should be distributed with the first draft of the regulation in order to maximize the opportunity for public input; and

(6) that in organizing public meetings, it would be preferable if the Ministry could distribute all relevant materials to participants prior to the actual dates of the meetings.

I shall certainly give serious consideration to the feasibility of incorporating those suggestions which are not now part of our processes. Certain of the suggestions are already part of the procedures. For example, the preparation of a statement of the rationale for choice of exposure limits is an integral part of the current process. In addition, comments on the criteria adopted for lead have been included as part of the background material supporting the lead regulation.

All definitive and relevant information available will be incorporated in the background material for a proposed regulation.

Certain economic information is collected at an early stage in the process leading to the development of designated substances regulations. The difficulties associated with a Ministry initiated in-depth economic impact study in relation to every designated substance are referred to in the document "Assessing the Impact of Designated Substances Regulations" which has been provided to Council. We anticipate that in most instances, respondents will provide their own economic data and impact analysis when replying to proposed regulations. Indeed we see this as one of the major reasons for publishing the proposed regulation in advance: i.e. to give respondents the opportunity to alert the Ministry to significant cost implications on a firm-by-firm basis. Material supplied by respondents will be assessed by the Ministry and the assessment will be part of the compendium of information available to interested parties.

It is our intention that where a code is referenced in a proposed regulation it will be available at the time of publication. I would point out that in the case of the lead regulation, the codes in existence when the proposed regulation was published in August 1980 were modified substantially in the light of briefs and comments received subsequently. Nonetheless, I agree with your suggestion that all documents incorporated by reference in a regulation should be available at the time of original publication.

While Council's suggestion that the Ministry distribute relevant material in advance of public meetings has considerable merit, I should advise you that the Ministry made a deliberate decision to provide key documents, with an oral explanation, at the meetings and to allow a further period for reflection and comment by interested parties. It was thought desirable that parties should have the opportunity to hear the Ministry's oral explanations of changes in the regulation and incorporated documents as well as the full rationale for those changes, at the time of their distribution.

lead concentration at which to remove from exposure women capable of bearing children, in order to protect the developing foetus. This lower level is based upon medical evidence which indicates that lead exposure is more harmful to children under 4 years of age.

3. Whether a lower exposure limit could be achieved without imposing significant additional economic costs

The blood lead level of 0.70 mg/L and the airborne lead level of 0.15 mg lead per m^3 were selected on the basis of the best health evidence available to the Ministry. The reasons for the selection of these levels are detailed in my letter of June 3, 1981, (and attachments).

Only after the Ministry had determined the appropriate exposure levels for blood and airborne lead on the basis of health effects evidence was the question of economic impact considered. As the document entitled "Assessing the Impact of Designated Substances Regulations" indicated, complex economic impact studies would be costly and time-consuming and may be justified only where an initial evaluation of the impact of the target levels indicate the likelihood of adverse consequences to affected users. As I have said earlier, in most instances I would hope that respondents would provide detailed material relating to the impact of the regulation on their operations following the publication of the proposed regulation, which the Ministry could then consider and analyze. In the view of the Ministry, levels should continue to be determined initially on the basis of health considerations. Moreover, I must say that I do not necessarily agree with the suggestion that levels lower than those justified on the basis of the best available health studies should be chosen simply because such levels could be achieved without imposing "significant additional economic costs".

4. Lowering the action level in the Code

The 0.60 mg lead/L blood action level found in The Code for Medical Surveillance for Lead is a minimum standard which, I am advised, is consistent with the evidence of minimal health effects in the literature. Action by a physician below that level is, of course, not precluded, particularly if symptoms are apparent.

5. The review of exposure levels

On-going assessment is an integral part of the continuing review process.

Council also questioned four areas relating to the analytical and legal/technical aspects of the regulatory process:

I believe that most of those attending the meetings thus far have found this approach to be helpful in avoiding confusion and misconceptions. However, I shall review the process with my staff in light of your suggestions.

In addition to commenting on the consultative process, Council has also commented on the soundness of the analytical process and the legal-technical aspects of the regulatory process with respect to lead. Council has raised five issues of specific concern. These include:

(a) the need for a more detailed form of risk assessment;

(b) the basis for the Ministry's decision to set a different blood lead concentration for removal from exposure to lead of women capable of bearing children from that for all other workers;

(c) whether the allowable exposure to lead could be reduced without imposing significant additional economic costs upon lead users;

(d) whether the Ministry should have taken into account the uncertainties that exist about desirable levels of control for occupational exposure to lead in framing the regulations and codes; more specifically, whether the Ministry should give consideration to lowering the 0.60 mg/L action level for "enquiries regarding work practices and personal hygiene," found in section 4(1) (a) (i) of The Code for Medical Surveillance for Lead; and

(e) whether the Ministry should regularly review the control levels specified in the regulation and codes and make appropriate changes as additional knowledge is acquired.

1. The need for a more detailed form of risk assessment

The Ministry carefully reviewed all available data in developing the health effects document for lead. The mathematical model in the risk assessment approach recommended by Council was not feasible since suitable data are not available for the conduct of a risk assessment specific to Ontario. It is estimated that this process, i.e. the assembly of the data and the application of a mathematical model to it, would take some years to complete. Despite these problems, I have asked my staff to consider all ramifications of the proposal and let me have their considered views.

2. The basis for Ministry's decision to set different permissible limits for blood lead concentrations for women capable of bearing children compared with all other workers.

Based on the data reviewed by the Ministry, the blood lead level adopted for removal of all workers from exposure, except for those women capable of bearing children, was 0.70 mg/L. However, since 1978, consideration has been given to adopting a 0.40 mg/L blood

(1) Does a Ministry inspector have the authority to order an employer to conduct a workplace assessment when the employer claims that the regulation does not apply to his workplace?

(2) Is there a need to define precisely the meaning of the terms "hygiene practices, work practices and engineering controls" in section 4 of the regulation, and similar phraseology in section 1 of *The Code for Medical Surveillance for Lead*?

(3) Should *The Code for Medical Surveillance for Lead* provide that two blood lead tests be required before a worker who has been removed from work because of exposure to lead is permitted to return to work?

(4) Should a formal scheme of financial compensation over and above that provided under *The Workmen's Compensation Act* be implemented to protect workers who have been removed from work because of exposure to lead?

The Ministry's views on these issues are as follows:

(1) With respect to the issue of an inspector's power to order an employer to conduct a workplace assessment, sections 3,6, and 9 apply.

Section 3(1) provides that the regulation ".... applies to every employer at a workplace where lead is present, produced, used, handled or stored and at which a worker is likely to inhale, ingest or absorb lead." Section 6(1) compels every employer to whom the regulation applies to cause an assessment of the exposure, or likelihood thereof, in the workplace, to be made. Section 9(1) provides that where a dispute as to an assessment arises, between an employer and either the workers themselves or the joint health and safety committee, an inspector may be notified, whereupon the inspector shall investigate and give a decision in writing. However, should the circumstances require further action on the part of the inspector in order to ensure compliance with the requirements of the regulation, the inspector retains the power to issue an order for a contravention of any section of the Regulation (see section 9(2)). Consequently, if the Regulation applies to an employer and that employer improperly refuses to conduct an assessment as required by the Regulation, an inspector can issue an enforceable order with respect to the failure to conduct such an assessment. This order would be subject to the usual appeal procedures specified in the Act.

(2) The Ministry is of the opinion, supported by legal advice, that it is not necessary to define the terms "hygiene practices", "work practices" and "engineering controls". Definitions which purport to be exhaustive might inadvertently limit or restrict the generality of those terms. Council might care to clarify for the Ministry its concerns regarding the phraseology in section 1 of The Code for Medical Surveillance.

(3) The Code requires that a worker's blood lead level must fall to 0.50 mg/L or less before the worker is allowed to return to work. It is considered that one test result at this level is sufficient to protect the worker since 0.50 mg/L is significantly below the critical blood lead level and thus provides a substantial margin for error adequate to ensure the protection of the worker in each case.

(4) The issue of compensation over and above that provided under The Workmen's Compensation Act is a matter which is beyond the regulation-making authority of the Ministry. Consequently, Council may wish to make its views in this regard known to Professor Weiler who is addressing the question of compensation for industrial disease as part of the second phase of his inquiry into The Workmen's Compensation Act.

Finally, may I express my sincere appreciation for the exhaustive examination undertaken by Council, and for the constructive comments and advice contained in your memorandum. I think it is recognized that the control of toxic substances is one of the most important and complex tasks in the field of contemporary governmental regulatory activity. I am indebted to Council for its care and diligence in assisting in this vital endeavour. The process is an evolutionary one, and can, I am sure, be refined and improved as we proceed with other substances. I know that I can continue to count on your Council in this vital collaborative endeavour.

Yours very truly,

Robert G. Elgie, M.D.
Minister

Advisory Memorandum 81-II

Ontario

Advisory Council on
Occupational Health &
Occupational Safety

Office
of the
Chairman

400 University Avenue
Toronto, Ontario
M7A 1T7
416/965-2448

November 4, 1981

Honourable R. G. Elgie, M.D.,
Minister of Labour,
14th Floor,
400 University Avenue,
Toronto, Ontario.
M7A 1T7

Dear Dr. Elgie:

On behalf of the Advisory Council, I am pleased to submit council's Advisory Memorandum 81-II on Prevention in Occupational Health and Safety through the Workmen's Compensation Board and its Accident Prevention Associations.

As you know, council has received and considered briefs submitted by the accident prevention associations and the Council of Safety Associations as part of a series of open meetings and consultations with them in respect to their future role in prevention under the workmen's compensation legislation.

In the advisory memorandum which council now submits for your consideration, certain recommendations are made which will have a bearing on the Workmen's Compensation Board, the accident prevention associations, management and labour. During our discussions, council members considered the desirability of this advisory memorandum being distributed to all interested parties for comment before being submitted to you. It is the majority view of council that our advice should be based upon our best judgment, following the consultations we have established with the Workmen's Compensation Board and the accident prevention associations, and that it should be left to your good offices to review and consider the recommendations in any manner which you think is appropriate. Council recommends, however, that you hold the customary consultations with all groups that would be affected by the implementation of any of these proposals, in order to ensure maximum support for and understanding of any changes to be made in this area.

Council looks forward to receiving your response.

Yours truly,

J. F. Mustard
Chairman

Attach.

Note: One member of council, Mr. J. Gill, could not support the basic proposals set forth in the Advisory Memorandum, and wished to have it so recorded.

Advisory Memorandum 81-II
to the Minister of Labour
November 4, 1981

On Prevention in Occupational Health and Safety through the Workmen's Compensation Board and its Accident Prevention Associations

INTRODUCTION

The accident prevention associations are semi-autonomous voluntary organizations set up by employers under the provisions of the *Workmen's Compensation Act*. While their primary role is education and consultation in accident prevention, they are playing an expanding role in occupational health and hygiene. The associations work together on the Council of Safety Associations, co-operate with each other through exchange of expertise and have working relationships with several government ministries. The participation of labour is included by many associations as a program element. Some have established advisory or liaison committees like the IAPA — OFL Liaison Committee or the Labour Management Committee on which EUSA sits or the CSAO's Labour Management Committee.

The accident prevention associations in Ontario were originally based on the model of the German insurance institutes. However, it was not clear from the wording of the *Workmen's Compensation Act* of 1914[1] whether they were to play the same role in Ontario as was played by the insurance institutes in Germany, which formulated and enforced accident prevention rules.

In 1964, the Act was amended, following recommendations by Mr. Justice McAndrew,[2] to bring the accident prevention associations under the direction and jurisdiction of the Workmen's Compensation Board. The associations were given a role in education, but the government clearly had the responsibility for inspection and enforcement of its regulations.

There are, at present, nine accident prevention associations established under section 119 of the *Workmen's Compensation Act*. This section states:

> 119 (1) The employers in any of the classes for the time being included in Schedule 1 may, with the approval and under the control of the Board, form themselves into an association for the purpose of education and accident prevention.
>
> (2) If the Board is of the opinion that an association formed sufficiently represents the employers in the industries included in the class, the Board may approve rules of operation and, when approved by the Board and by the Lieutenant Governor in Council, they are binding on all the employers in industries included in the class.
>
> (3) Where an association under the authority of its rules of operation appoints an inspector or an expert for the purpose of education in accident prevention, the Board may pay the whole or any part

of the salary or remuneration of such inspector or expert out of the accident fund or out of that part of it that is at the credit of any one or more of the classes as the Board considers just.

(4) The Board may, in any case that it considers proper, make a grant towards the expenses of any such association.

(5) Any moneys paid by the Board under this section shall be charged against the class represented by such association and levied as part of the assessment against such class.

(6) The word 'class' in this section includes subclass or such part of a class or such number of classes or parts of classes in Schedule 1 as may be approved by the Board.

R.S.O. 1970, c. 505, s. 119

The nine associations are: (showing year when each was formed)

- 1915 - Electrical Utilities Safety Association;
- 1915 - Forest Products Accident Prevention Association (formerly Lumbermen's Safety Association);
- 1915 - Ontario Pulp & Paper Makers Safety Association;
- 1917 - Industrial Accident Prevention Association;
- 1929 - Construction Safety Association (reorganized in 1938);
- 1930 - Mines Accident Prevention Association;
- 1942 - Transportation Safety Association (formerly Class 20 APA);
- 1968 - Hospital Occupational Health and Safety Services (Department of the Ontario Hospital Association); and
- 1973 - Farm Safety Association.

The nine accident prevention associations cover approximately two million employees out of an employed labour force of about four million. Statistics on the number of companies and employees served by the individual associations indicate a considerable heterogeneity in the size of these operations. Such statistics are to be found in the Safety Associations Table of Services Provided — September 1978, in council's second annual report.[3]

The classes of industry under Schedule 1 of the Act which have not exercised their option to form themselves into associations include:

- boards, commissions and municipal boards;
- fishing companies;
- hotels;
- catering companies;
- office buildings;
- wholesale mercantile packaging companies;
- theatres;
- professionals; and
- security services.

A large number of Schedule 2 employers, who are individually liable to pay compensation and medical aid are also not covered. Other industries not covered by accident prevention associations are those excluded, under regulation 834, from Part I of the Act. These are:

- barbering and shoe-shining establishments;
- educational work, veterinary work and dentistry;
- funeral directing and embalming;
- the business of a photographer;
- taxidermy; and
- permanent employees of the Fire Department of the City of Toronto who are under the Toronto Fire Department Superannuation and Benefit Fund.

Council's second annual report contained a discussion paper on the future of the accident prevention associations, together with the responses of the individual associations. Council has met with each association and has held a special meeting with the Council of Safety Associations. At that meeting, held in October 1980, the following points were discussed:

- — the role and objectives of the Council of Safety Associations;
- — its relationship with individual associations;
- — its relationship with the Workmen's Compensation Board and the role of the chairman of the Council of Safety Associations;
- — the extent of industry coverage; and
- — accountability and wider representation.

The Council of Safety Associations presented a formal response dealing with these points.[4] This response helped greatly to clarify the position of the Council of Safety Associations.

The Advisory Council has also had the opportunity to study Professor Weiler's report *Reshaping Workers' Compensation for Ontario*[5] and the *Government White Paper on the Workers' Compensation Act*.[6] Both these documents have important implications for some of the points which council will consider.

As a result of these meetings, consultations and further deliberations, council remains impressed by what has been achieved through the accident prevention associations under the Workmen's Compensation legislation. A good base has been established from which the fundamental issues can be addressed in keeping with the philosophy expressed in the *Report of the Royal Commission on the Health and Safety of Workers in Mines*[7] (the Ham Report) and in the *Occupational Health and Safety Act*.

Council would like to repeat its recognition of the value of the associations as expressed in its letter to the Minister of Labour, dated March 14, 1980:

> 'During the course of its consultations with the associations, the council was impressed by the manner in which they evolved by responding to new challenges. Each association defines its objectives to meet the particular needs of its industry or industries. The voluntary initiative by employers and employees in defining problems and seeking the assistance of the appropriate accident prevention association is the cornerstone of their collective success. It is the council's belief that nothing should be done which destroys this voluntary initiative. Having assured you of the associations' value, the Advisory Council emphasizes the importance of facilitating the continuing evolution of a vigorous Council of Safety Associations. The associations have many programs in common. They have

> the same interests at heart. There may be certain functions which can be accomplished more effectively through a central office. These program-based considerations are probably quite important for the growth of the Council of Safety Associations, which was only established in 1974. The issues of coverage, accountability and wider representation also require attention.'

As a result of its discussions with the various safety associations and with the Council of Safety Associations, council has been able to identify the following major areas of concern: prevention, coverage, accountability and representation. There are at least four ways these issues might be addressed:

1) by having the ministry take over the role of the accident prevention associations;
2) by creating a new board or commission or ministry responsible for all aspects of occupational health and safety;
3) by restructuring and strengthening the role of the Workmen's Compensation Board in prevention in occupational health and safety; or
4) by allowing the existing structures to evolve.

The first two options described above would require major legislative changes in relation to the associations as they are constituted under the *Workmen's Compensation Act*. Council is convinced that any attempt to alter the structures or procedures of the accident prevention associations primarily through a process of new legislation would be counter-productive in that it would destroy the valuable components of participation and commitment, which are characteristic of the spirit of these associations.

We have witnessed, over the past number of years, a steady move, supported by legislation, toward a more co-operative labour-management approach to solving the health and safety problems associated with the workplace. Council believes that the ministry and the Workmen's Compensation Board should do whatever is possible to optimize this process and avoid any moves which might threaten the spirit of co-operation and voluntarism upon which the associations have thrived.

Because council feels that change must come about through a process of evolution, it believes that the fourth option, described above, represents the most appropriate strategy at this time. In this advisory memorandum, council gives consideration to what should be done within the existing structures to bring about the desired changes. It will also make suggestions on how a restructured Workmen's Compensation Board might play an important role in facilitating these developments.

The following topics will be considered: prevention, coverage, representation and accountability.

1. Prevention

There are three areas of activity traditionally associated with the Workmen's Compensation Board. These are: prevention, compensation and rehabilitation. Over the years, the board has, with reason, given the major thrust to compensation and rehabilitation as these are its own activities. Prevention has not been stressed internally by the board, possibly because it has felt that the accident prevention associations carried out that responsibility (albeit under the board's legislative authority). Council believes that consideration should now be given to placing considerably more emphasis on the preventative function and to integrating it with the other two functions of the board. In the assessment levy and proposed experience rating schemes, the board has a potentially effective method of encouraging individual companies to reduce their accident rates, as a means of reducing their payments. Council believes that the board should continue to use the members and staff of the safety associations for their accident prevention expertise in the field of counselling, research and education, but that it should also assume more direct interest, involvement and responsibility in this area than has been the case to date.

ACOHOS RECOMMENDATION 81-1

> that the Minister of Labour take measures to ensure that the direct responsibility of the Workmen's Compensation Board in the area of prevention in occupational health and safety be clearly spelled out in the legislation.

At the present time, prevention programs in occupational health and safety in the province are administered by a variety of organizations, including the accident prevention associations, labour organizations and industry. In order for the board to convince these very disparate groups that it can adequately assume legislative responsibility for prevention, there will need to be some restructuring of the board itself.

The *Government White Paper on the Workers' Compensation Act* makes a number of proposals for the restructuring of the corporate board.[8] For example, it proposes that the composition be changed to provide a variety of perspectives by appointing a number of outside directors who would reflect the points of view of labour, management, medicine, vocational rehabilitation, occupational health and safety, and the economics of income maintenance.

Council believes that it would be desirable for one of the directors of the board to have primary responsibility for occupational health and safety, including the programs and achievements of the accident prevention associations, and to be suitably qualified and experienced in that area. The inclusion on the board of a director with such expertise would focus attention on the importance of prevention in occupational health and safety.

> that the Minister of Labour ensure that at least one of the directors of the Workmen's Compensation Board be selected for appointment on the basis of his or her qualifications and experience in the field of occupational health and safety and that one of the directors with such qualifications and experience have primary responsibility for occupational health and safety, including the programs and achievements of the accident prevention associations.

2. Coverage

As stated in the Introduction to this advisory memorandum, approximately half of the employed labour force in Ontario is covered by the existing accident prevention associations. Given the importance that council attaches to the prevention function, and the essential role that it believes the associations can play in this area, council must now consider the scope and range of the existing coverage.

The Council of Safety Associations, in its discussions with the advisory council, made the point that it is not its responsibility to decide on the scope and range of coverage and that such questions should be directed to the Workmen's Compensation Board. Some of the members of the Council of Safety Associations felt that there was no need for change in the extent of coverage. However, the advisory council was pleased to learn that this topic was one which could be considered by the Standing Committee on Organization and Objectives, which the Council of Safety Associations intends to establish.

It is generally accepted that a key to occupational health and safety is prevention. If prevention of accidents and occupational disease is to occur throughout industry and if one way of achieving this is through education and training programs which are universally available, then the organizations responsible for these programs must have a wider jurisdiction. Council believes that the accident prevention associations should continue to perform their very valuable aservices in the area of education and training. However, in order to ensure that maximum benefit is derived from these programs, the system of coverage must be extended so that the associations may have greater access to the workforce. Comprehensive and complete coverage by accident prevention associations should be established as the ultimate goal. Until such time as complete coverage can be achieved, the Workmen's Compensation Board should set up a mechanism for ensuring that those areas of industry not served by accident prevention associations have access to education and training programs funded through the board.

As was pointed out by the Construction Safety Association in its commentary on the discussion paper, some of the companies in Schedule 1 of the *Workmen's Compensation Act* which are not covered by accident prevention associations have very low accident frequency rates. This would suggest that expansion of coverage should be done on a priority basis, taking into account the injury frequency of the rate groups of companies and risk of worker exposure to health hazards.

One area in particular where the minister might take independent action to ensure that appropriate coverage exists is in employment by or under the Crown in right of Ontario and any employment by a permanent board or commission appointed by the Crown in right of Ontario. Such employment is now listed under Schedule 2 of the *Workmen's Compensation Act* and is, therefore, not covered by section 119 of that Act. It should be noted that the *Occupational Health and Safety Act*, section 2(1) binds the Crown and applies to an employee in the service of the Crown or an agency, board, commission or corporation that exercises any function assigned or delegated to it by the Crown.

ACOHOS RECOMMENDATION 81-3

> that the Minister of Labour request the Workmen's Compensation Board to ensure that the coverage of the accident prevention associations be extended and that health and safety training and education services be provided for the industries, including those in Schedule 2, which are not covered by the associations, and where adequate health and safety programs are not already in place.

In council's deliberations with the accident prevention associations, it was apparent that most are concerned about the risks to health in the workplace, as well as safety. Council is concerned that the appropriate emphasis be placed on the various aspects of the associations' programs, depending upon the type of industry to be serviced.

Council recognizes one of the difficulties inherent in any decision on the part of the ministry to encourage the expansion of the existing programs of the accident prevention associations rather than to have the ministry itself assume direct responsibility in these areas: the accident prevention associations do not have an automatic entrée to all the companies in the various industrial sectors. Council is well aware that the success or failure of the present system will depend not only upon the arrangements for and the quality of the programs offered but also upon the incentives for industry to take advantage of these services.

ACOHOS RECOMMENDATION 81-4

> that the Minister of Labour ask the Workmen's Compensation Board to take steps to ensure that the occupational health, safety and hygiene programs of each of the accident prevention associations have been developed in a suitable manner for the industries in the class and are being appropriately delivered to them, and, further, to ensure that the associations have access to the requisite technical and medical expertise. The minister should encourage industry to take advantage of these programs.

One of the concerns of the advisory council has been the provision of services for small businesses. (See Advisory Memorandum 79-I).[9]

Council was impressed by the excellent services offered to small business by the Farm Safety Association, the Forest Products Accident Prevention Association, the Electrical Utilities Safety Association and the Industrial Accident Prevention Association.

Council trusts that continuing efforts will be made to implement the policies set forward in ACOHOS Recommendations 79-5 and 79-8.[10]

3. Representation

Among the more difficult subjects in our discussions with the accident prevention associations and the Council of Safety Associations was the subject of the relationship between management and labour in the operations of the accident prevention associations. In some instances, for example in the Construction Safety Association and in the Industrial Accident Prevention Association, joint management and labour groups have been established at the operating level. However, none of the associations has specifically recruited representatives from organized labour for its board, although some have individuals with a labour background.

As early as 1950, Mr. Justice W. D. Roach, in his report on the *Workmen's Compensation Act,* criticized the system for not ensuring the active participation of labour in accident prevention.[11] This criticism was made again in 1960 by the Royal Commission on Industrial Safety (the McAndrew Commission).[12] In 1965, the Labour Safety Council of Ontario, in its report on Accident Prevention and Safety Education in Ontario, recommended the appointment of labour representatives to the boards of directors of the accident prevention associations.[13]

In 1976, the *Report of the Royal Commission on the Health and Safety of Workers in Mines*[14] addressed the issue of joint management and labour participation in occupational health and safety and encouraged its development as rapidly as possible.

The *Occupational Health and Safety Act* articulates clearly, in formal legislation, the concept of joint labour-management participation and shared responsibility. More recently, Weiler's Report[15] has again emphasized the need for broad representation on a body such as the Workmen's Compensation Board.

Similar arguments have recently been put forward in the Report of the Joint Federal-Provincial Inquiry Commission into Safety in Mines and Mining Plants in Ontario (the Burkett Commission).[16]

The commission, in discussing the matter of financial resources, which come from employer members of the associations through the Workmen's Compensation Board levy, made the following comments:

> 'The belief that financial support entitles the industry to exclusive control over the programs and performance of the association is false.'

It went on to argue that:

> 'In the first place, the industry is the direct beneficiary of the service and, as such, should be expected to assume the financial burden. More importantly, we view the levy charged for the operation of the association as part of the "historic trade-off" which underpins the workmen's compensation system in Ontario.'[17]

This trade-off consists of the removal of the employee's right to sue an employer in court for damages in return for guaranteed protection against income loss due to industrial injury.

The commission recommended that the Mines Accident Prevention Association establish labour-management advisory committees at both the provincial and regional levels, and that it move to include representatives of labour and the public on its board of directors.[18] (Council does not propose, at this stage, to discuss the role of the public in connection with the accident prevention associations).

The commission felt that the involvement of labour in the delivery of education in accident prevention would bring about broader based support for the activities of the associations.

Council recognizes that the accident prevention associations are actively addressing the issue of labour participation. It has noted, however, that it has not been a priority of all the associations and all elements of organized labour to establish co-operative representation. Council believes that a means of progressing towards participation should be found.

Education and training programs jointly run by management and labour must be a long-term goal and, in striving for this, some direction and guidance must be given to the accident prevention associations and the other organizations actively involved in occupational health and safety. However, council is of the view that any direction or guidance must, for the present, be aimed at facilitating the development of sufficient understanding and trust between management and labour to lead to the establishment of effective joint programs in prevention.

If the organization and funding of prevention programs could be structured in such a way that management and labour were equal partners in establishing, operating and reviewing the appropriateness and effectiveness of those programs, we would be a long way toward implementing the joint responsibility approach to occupational health and safety problems. However, a key question in many sectors of industry is how to build the trust that would allow for the effective establishment of joint labour-management programs. The inclusion of labour members on the boards of directors of the accident prevention associations could not, by itself, guarantee for labour an equal voice in the planning and direction of health and safety programs. There would have to be corresponding changes made in the staffing and structure of the associations. Since it is unlikely that such extensive reorganization would be acceptable or feasible at the present time, some other means must be devised of ensuring an equal role for labour. Working partnerships between management and labour will only be effective when they are established on terms satisfactory to both sides. Until this is achieved, maintenance of the independent capability of labour organizations in this field is one way of ensuring that labour does not feel it is being excluded in the area of prevention.

The Construction Safety Association might well be in a position to participate in the setting up of joint programs because of the long experience it has had in working, through its Labour Management Committee, on the safety problems in the construction industry. In those industries that have not established these working relationships and an accompanying sense of trust, difficulties will be encountered. It is council's view that the Workmen's Compensation Board should actively promote jointly-run programs in those areas that are ready for this change. The problem remains of what to do with those sectors in which labour and management are not ready for the establishment of joint arrangements on a *voluntary* basis.

One option is, of course, to do nothing and hope that progress in a few of the accident prevention associations will encourage change in others. However, the lack of progress in some sectors over the past thirty years, despite the various recommendations with regard to joint management-labour participation, leaves one with little hope that significant change will result from this approach.

One area in which an example of participation might well be given is at the level of the Council of Safety Associations. Equal management and labour representation on this body could, perhaps, lead to a change of attitude among all the participants in the field.

It would be desirable if the members of the Council of Safety Associations were appointed by the Workmen's Compensation Board from names recommended by the accident prevention associations and labour.

A further step toward the goal of joint management-labour participation might be taken by the Workmen's Compensation Board, which, through a restructured Council of Safety Associations, might strike joint task forces, composed of representatives drawn from the appropriate accident prevention associations and from the relevant labour organizations, to deal with specific problems. While this approach would be far from ideal, it would be a step in the right direction, provided all understood that the ultimate goal was to establish programs in occupational health and safety jointly run by management and labour. An evolutionary step in this direction might involve the development of joint* labour-management boards of directors of some accident prevention associations.

In order to facilitate the setting up of joint task forces, the Ministry of Labour, in collaboration with the Workmen's Compensation Board, could agree to fund labour programs in occupational health and safety. There has been initial recognition of the need to support labour endeavours in this area. (The OFL's training program is presently supported from the lottery funds.) Equality of treatment requires not only recognition and encouragement of labour's independent capabilities in this area, but also financial support. The resources made available to labour must be such that it is given an equal opportunity to develop its understanding and skills in prevention. After careful consideration, it may be found necessary to provide more funds than those provided to the accident prevention associations.

In the above context, any undertaking to fund the OFL and other labour programs in the immediate future would call for a clear understanding of the temporary nature of the arrangement and for a commitment to the ultimate goal of joint labour-management participation in occupational health and safety programs. Similarly, the continuation of the current funding arrangements for the accident prevention associations under the Workmen's Compensation Board could be made conditional upon their commitment to this ultimate goal of a collaborative approach to prevention. At the end of five years, the funding arrangements should be reviewed and future directions established in consultation with labour and management groups.

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*i.e. where labour and management sides have equal voting powers.

A portion of the funding for the labour programs could be derived from the Workmen's Compensation Board. In addition, the board might set aside part of the funds now used to support the accident prevention associations for the support of joint management and labour programs sponsored by the associations and labour. The Ministry of Labour should give consideration to providing the additional short-term financial support needed to facilitate these evolutionary developments.

ACOHOS RECOMMENDATION 81-5

> that the Minister of Labour encourage the Workmen's Compensation Board to establish, as soon as possible, a balanced participation of labour and management on the Council of Safety Associations.

ACOHOS RECOMMENDATION 81-6

> that the Ministry of Labour ask the Workmen's Compensation Board, through its Council of Safety Associations, to enter into appropriate arrangements with labour and the accident prevention associations in order to facilitate the development of management-labour task forces to deal with specific problems and to facilitate the development of occupational health and safety training programs jointly run by management and labour.

ACOHOS RECOMMENDATION 81-7

> that the Minister of Labour, in collaboration with the Workmen's Compensation Board, establish appropriate continuing arrangements for reviewing and funding labour programs in occupational health and safety, such as the Ontario Federation of Labour program, until such time as new arrangements for joint management and labour training programs are established. The resources made available for funding such programs should be such that labour is given an equal opportunity to develop its understanding and skills in prevention.

4. Accountability

If prevention is to be improved and if the objective of joint labour-management representation is to be achieved, the Workmen's Compensation Board must exercise its responsibility in this area by establishing a clear set of objectives and measures for assessing whether these objectives are being met.

The accident prevention associations assist the board to fulfil its mandate in prevention and they, in turn, need the full support of the board in order to achieve their objectives. It is therefore in the interest of both the board and the accident prevention associations to strengthen the ties between them and to continue to improve the arrangements by which the board reviews the programs and achievements of the associations.

The Council of Safety Associations has provided a framework within which the individual associations have continued to develop. Because of the increasing complexity of occupational health and safety issues, many of which cross industrial boundaries, it is important that this framework be strengthened and that the council's co-ordinating function be enhanced. If the Workmen's Compensation Board is to assume more direct responsibility in the area of prevention, it is important that it study the role of the Council of Safety Associations. It would be advantageous for the board to examine not only the relationship between the individual associations and the Council of Safety Associations, but also the relationship of the council to the board itself. The Council of Safety Associations might be a vehicle through which the board could enhance the ties and accountability of the accident prevention associations to the board.

In the Council of Safety Associations' brief to the advisory council,[19] two important points were made. It was suggested that the council be restructured and its terms of reference and operating procedures be modified so that: 1) 'The Council (of Safety Associations) has a clear task of establishing overall objectives for the general guidance of the member safety associations,' and 2) 'The Council achieves a formal means of exchanging information with the Workmen's Compensation Board about overall objectives and activities.'

Council believes it is important that the board recognize the merit of these constructive suggestions, which would serve to strengthen the relationship between the accident prevention associations, the Council of Safety Associations and the Workmen's Compensation Board. The implementation of these objectives could serve to enhance the arrangement by which the board supports, participates in and reviews the programs and achievements of the accident prevention associations.

In establishing these new arrangements for the Council of Safety Associations, consideration should be given to the role of the chairperson of the council and his or her relationship to the board. One arrangement which would certainly enhance the visibility of prevention at the level of the board would be for one of the directors of the board with qualifications and experience in occupational health and safety to be appointed, by the board, as chairperson of the council. Such an arrangement could have a significant effect upon the board's review of the programs and achievements of the accident prevention associations.

The council itself, in its brief to the advisory council,[20] suggested that the chairperson be elected from the active members of the accident prevention associations for a term of not more than two years. The relationship between the board and a chairperson selected in this manner would obviously be quite different from the relationship that could exist if the chairperson were appointed by the board, as recommended below, for a longer period of time. In the latter case, the board would have a greater influence upon the direction and focus of the council and would be in a position to develop and more effectively implement long-term policies in the field of prevention.

ACOHOS RECOMMENDATION 81-8

that the Minister of Labour ask the Workmen's Compensation Board and the accident prevention associations to strengthen the relationship between the associations, the Council of Safety Associations and the board, so as to enhance the board's review and understanding of the progress and achievements of the associations.

ACOHOS RECOMMENDATION 81-9

that the Minister of Labour encourage the Workmen's Compensation Board to endorse the proposals, set forth in the Council of Safety Associations' brief to the advisory council, for a broadened role for the Council of Safety Associations. In particular, council recommends that the minister encourage the implementation, within the framework of ACOHOS Recommendation 81-8, of the following two proposals:

1) that the Council of Safety Associations should have a clear task of establishing overall objectives for the general guidance of member safety associations;
2) that the council should achieve a formal means of exchanging information with the Workmen's Compensation Board about overall objectives and activities.

ACOHOS RECOMMENDATION 81-10

that the Minister of Labour recommend to the Workmen's Compensation Board that one of the directors of the board with qualifications and experience in occupational health and safety be appointed by the board as chairperson of the Council of Safety Associations.

Council recognizes that these recommendations will not satisfy all parties. However, they are, in council's view, in keeping with the philosophy of the Ham Report and with the intent of the *Occupational Health and Safety Act*.

Footnotes

1. Statutes of Ontario, 4 Geo. V, 1914, c.25.
2. Royal Commission on Industrial Safety, Report (Toronto, 1961).
3. Second Annual Report of the Advisory Council on Occupational Health and Occupational Safety, p.242.
4. Third Annual Report of the Advisory Council on Occupational Health and Occupational Safety, p.266.
5. Paul C. Weiler, Reshaping Workers' Compensation for Ontario, Report (Toronto, 1980).
6. White Paper on the Workers' Compensation Act, Government of Ontario (1981).
7. Royal Commission on the Health and Safety of Workers in Mines, Report (Toronto, 1976).
8. *Op. cit.* p.42.
9. Second Annual Report of the Advisory Council on Occupational Health and Occupational Safety, p.30.
10. *Ibid.* pp.42 and 44.

11. Royal Commission on the Workmen's Compensation Act, Report (Toronto, 1950) p. 91.
12. *Op. cit.* pp. 19-21.
13. Accident Prevention and Safety Education in Ontario, Report of the Labour Safety Council of Ontario (Toronto, 1965) pp.25-26.
14. *Op. cit.*
15. *Op. cit.* p.130.
16. Towards Safe Production, Report of the Joint Federal-Provincial Inquiry Commission into Safety in Mines and Mining Plants in Ontario (1981).
17. *Ibid.* p.100.
18. *Ibid.* p.108.
19. *Op. cit.*
20. *Op. cit.*

Acknowledgements

Council wishes to acknowledge the assistance given by the accident prevention associations and by the Council of Safety Associations in providing information on the activities and achievements of the associations and in offering constructive and thought-provoking comments on the various considerations put forward by council in its Second Annual Report.

Ontario
Advisory Council on
Occupational Health &
Occupational Safety

Office
of the
Chairman

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February 11, 1982

Honourable R. G. Elgie, M.D.,
Minister of Labour,
14th Floor, 400 University Avenue,
Toronto, Ontario.
M7A 1T7

Dear Mr. Minister:

It has been drawn to my attention that the wording of Advisory Memorandum 81-II can lead to some misinterpretation of the document. In order to avoid any misunderstandings, there are four points that I would like to clarify for you and your ministry staff. These concern:

1. The relationship between the proposals in this document and the Ham Report;
2. What we mean by the term 'labour';
3. What we mean by 'balanced participation of labour and management';
4. Our reference to the body having the responsibility for decisions on the levels of funding and accountability.

1. On page three of the advisory memorandum it is made clear that we wish to see the solution to the issue of prevention addressed within the philosophy of the Report of the Royal Commission on the Health and Safety of Workers in Mines. We repeat in the last sentence of the advisory memorandum our view that these recommendations are in keeping with the philosophy of the Ham Report and the intent of the Occupational Health and Safety Act.

   You will note that we emphasize in the top paragraph on page 66 that any arrangements which you introduce should be critically reviewed at the end of five years in the context of the ultimate goal of a collaborative approach to prevention.

2. We use a small 'l' for labour throughout this report so as to refer to all elements of labour, both organized and other. Where organized labour is identified, it is specifically referred to in the text as 'organized labour'. It would be important in the development of any joint management-labour programs to devise strategies whereby labour participation may adequately reflect the different kinds of labour groups that work in a particular field.

.....2

3. Similarly, when one talks about a balanced participation of labour and management on the Council of Safety Associations, it is important that the labour participation reflect to some degree the different kinds of labour groups that are involved in the various industrial sectors.

4. It is intended that Ministry funding arrangements be administered, if at all possible, through the Workmen's Compensation Board.

   Some concern has been expressed that the Advisory Council may not have adequately addressed the question of accountability in the use of any public funds for the support of labour programs in occupational health and safety. Recommendation 81-7 states quite clearly where responsibility for reviewing the activities in occupational health and safety prevention should reside. The accountability issue is specifically covered in Recommendations 81-7 and 81-8. Although we did not state specifically that the Council of Safety Associations is to be an advisory body, this was the intention. This should be emphasized since, with funding arrangements handled through the Workmen's Compensation Board, clearly program accountability must also be to the Board.

I hope that these comments will prove useful to the various groups that will have to consider the recommendations put forward. The chairman and members of the task force would be pleased to meet with any group that is concerned with the interpretation of the points made in the advisory memorandum.

We request that, if you release the report for discussion, you include this letter as part of the report.

Yours truly,

J. F. Mustard, M.D.,
Chairman.

c.c. Mr. T. E. Armstrong
Dr. A. E. Robinson

Office of the Minister

Ministry of
Labour

400 University Avenue
Toronto Ontario
M7A 1T7

March 23, 1982

Dr. J.F. Mustard, Chairman,
Advisory Council on Occupational Health and
Occupational Safety,
400 University Avenue, 15th Floor,
Toronto, Ontario, Canada,
M7A 1T7.

Dear Dr. Mustard:

Thank you for your letter of November 4, 1981, submitting to my predecessor, Dr. R.G. Elgie, M.D., Advisory Memorandum 81-II On Prevention in Occupational Health and Safety through the Workmen's Compensation Board and its Accident Prevention Associations. On February 11, 1982 you submitted a supplementary letter to the memorandum.

I recognize the importance of prevention in any occupational health and safety program and understand the essential role played by the Accident Prevention Associations in this area.

I am equally aware of the significance and desirability of increased labour participation in occupational health and safety matters through the encouragement and development of joint labour management ventures. As you are well aware, the Occupational Health and Safety Act clearly enunciates labour participation through worker health and safety representatives and joint participation through health and safety committees.

The Advisory Memorandum also contains recommendations concerning the industries which are not covered by existing associations, the role of the Council of Safety Associations, and the accountability of the safety associations to the Workmen's Compensation Board. These are diverse and far reaching recommendations which deserve broad public discussion by all concerned parties. Therefore, I plan to circulate your Advisory Memorandum and supplement to concerned parties with the expectation that they will submit written comments by the end of May 1982.

As you know, Professor Paul Weiler is engaged in the second phase of his study of the Workmen's Compensation Act. One aspect of his terms of reference involves the inter-relationship between The Workmen's Compensation Board and the Occupational Health and Safety Division of the Ministry of Labour. I believe that Professor Weiler is in the best position to review your advice in the context of his study. I have, therefore, asked him to review any submissions interested parties may wish to make on the Advisory Memorandum and report his findings to me.

I expect to be able to forward a formal response to Council as soon as the comments received have been analyzed.

Yours sincerely,

R.H. Ramsay
Minister

Advisory Memorandum 81-III

Office of the Minister

Ministry
of
Labour

400 University Avenue
Toronto, Ontario
M7A 1T7
(416) 965-4101

July 15, 1981

J. Fraser Mustard, M.D.,
Chairman,
Advisory Council on Occupational
Health and Occupational Safety,
15th Floor
400 University Avenue,
Toronto, Ontario

Dear Dr. Mustard:

I am pleased to forward the proposed designated substance regulation for mercury. I have also attached the Ministry's "Report on the Designation of Mercury in Ontario".

I look forward to receiving your reply at your earliest convenience.

Yours truly,

Robert G. Elgie, M.D.,
Minister.

Ontario

Advisory Council on
Occupational Health &
Occupational Safety

Office
of the
Chairman

400 University Avenue
Toronto, Ontario
M7A 1T7
416/965-2448

December 10, 1981.

The Honourable Robert G. Elgie, M.D.,
Minister of Labour,
400 University Avenue, 14th Floor,
TORONTO, Ontario. M7A 1T7

Dear Dr. Elgie:

On behalf of the Advisory Council, I am enclosing Advisory Memorandum 81-III in which council has reviewed the process for the development of the mercury regulation, in light of the policies and principles set out in Advisory Memorandum 78-II. In view of the useful information generated in the dialogue between council and your ministry, council suggests that this advisory memorandum and your reply thereto be made public at the same time that the regulation is promulgated.

Council is pleased to have participated in the process by which the final mercury regulation was developed.

Yours truly,

J. F. Mustard, M.D.,
Chairman.

Enc.

cc to: Mr. T. E. Armstrong
Dr. A. Robinson

Advisory Memorandum 81-III
to the Minister of Labour
December 10, 1981

A Review by the Advisory Council of the Process used to develop a Standard for Mercury and Council's Evaluation of the Criteria utilized to assess the Hazard of Mercury Exposure in the Workplace

INTRODUCTION

In February 1978, the advisory council and the then Minister of Labour agreed that council should be given the task of reviewing the principles and procedures used in setting occupational health standards and guidelines in Ontario. In Advisory Memorandum 78-II, council set out a list of the basic principles and procedures that should ideally characterize the policy process in respect to establishing standards, guidelines and codes. In this document, council undertook to review the criteria utilized by the Ministry of Labour to evaluate occupational health hazards and to follow the ministry's standard setting process through to its final form. It was also clearly understood that council would limit its review to the process leading to the development of ministry standards. In its memorandum, council also stated that it would require 30 days to complete its review function. In subsequent correspondence with the minister, it was agreed that, because of public interest in the area, council's review of the standard setting process should be submitted in the form of an advisory memorandum.

In June 1980, the Ministry of Labour published a Notice of Intent to designate mercury as a substance 'to which the exposure of a worker is prohibited, regulated, restricted, limited or controlled under the *Occupational Health and Safety Act*. This was followed, in August 1980, by a notice setting forth the ministry's proposed regulation for mercury. The notice invited public comments and stated that such comments would be made available for public examination. At the same time, the ministry distributed copies of the proposed regulation and three accompanying codes to interested members of the public. In October 1980, the ministry distributed a document entitled *Interim Report on the Designation of Mercury in Ontario*. This document dealt with such topics as the use of mercury in Ontario, workplace exposures to mercury, the control of such exposures and the health effects of mercury. Each interim report also contained a copy of the proposed regulation and codes. On May 28, 1981, the ministry held a public meeting to discuss changes that had been made to the August 1980 version of the regulation. A revised version of the proposed regulation and accompanying codes were distributed at this time, along with an entirely new Code for Medical Surveillance for Mercury. Invitees were told that they would have a short period of time to comment on any revisions that had been made to the regulation and codes.

On July 17, 1981, the ministry submitted to council a revised version of the mercury regulation, subject to any amendments that might be made as a result of submissions made by the public after the May 28 meeting. Included with the regulation was a document entitled *The Report on the Designation of Mercury in Ontario*. This document contained, among other things, a summary of the views expressed by members of the public on the various provisions contained in the first and second drafts of the regulation. The type of action taken by the ministry in response to the submissions made was also outlined. The background materials supplied to council did not contain an analysis of the type of economic impact that Ontario industry would likely experience if the provisions contained in the proposed mercury regulation were implemented.

Upon receipt of the regulation, council determined that it would submit its reply in two stages. On August 27, 1981, an interim letter was transmitted to the minister's office, which set out a series of issues that council felt merited further discussion. In this letter, council indicated that it would review the development of the mercury regulation according to three aspects of the standard setting process — the 'consultative process', the 'analytical process' and the 'legal-technical process'. The text of council's interim letter appears as Appendix I to this advisory memorandum.

In its interim letter, council asked that a meeting be arranged between council's Task Force on Regulations and ministry officials. The meeting was intended to fulfil two objectives. First, it would permit the ministry to reply, in detail, to the points raised in council's interim letter. Second, the meeting would allow task force members to explore, in greater depth, the rationale employed by the ministry to arrive at certain policy decisions. Such a meeting, for which detailed minutes were kept, took place on September 4, 1981.

On November 16, 1981, the minister replied to council's interim letter and noted that, as a result of the points raised by council and by others, some additional changes had been made to the regulation and codes. The letter also contained a detailed reply to the concerns outlined by council in its letter of August 27. On November 20, 1981, council received from the ministry a copy of the final revised version of the mercury regulation along with four accompanying codes. The minister's letter of November 16, 1981 is attached as Appendix II.

COUNCIL'S REVIEW OF THE STANDARD SETTING PROCESS FOR MERCURY

1. The Consultative Process

To reiterate the comments made in Advisory Memorandum 81-I, council wishes to commend the ministry for the steps it has taken to make possible public participation in the consultative process for the development of the mercury regulation. Council strongly endorses the ministry's effort to develop an open process for the setting of standards. Council is also cognizant of the special circumstances that surrounded the publication of the first seven designated substances regulations and the difficulty of adhering strictly to the procedures set out by council in Advisory Memorandum 78-II. In this regard, council notes that the Minister of Labour has undertaken, in his reply to Advisory Memorandum 81-I, to give serious consideration to a number of suggestions made by council to enhance the quality of the consultative process.[1]

Council wishes to make one additional point that relates to the consultative process for the development and promulgation of all designated substances regulations. During the September 4 meeting with ministry officials, task force members asked why the ministry had taken the position that only the final version of a designated substances regulation, and not the accompanying codes, should be published in the *Ontario Gazette*. In response, it was stated that the only document that must be filed with the Registrar of Regulations is the regulation. Furthermore, only those documents that are filed with the registrar can be gazetted.

Council has a number of reservations about the practice of not gazetting codes which, council understands, can be legally binding documents, if they are referenced in a regulation. The fact that such codes have not been gazetted would suggest that these documents could be amended without the need to gazette the changes. Council believes that this practice would detract from the openness of the process for developing standards. Council also believes that the segregation of the regulation from the codes in the *Ontario Gazette* could cause confusion with respect to the legal effect of the codes, since section 4 of the *Regulations Act* states that 'except where otherwise provided, a regulation [which includes a rule of a legislative nature] that is not filed has no effect.' On the basis of these considerations, council suggests that the ministry reconsider its decision not to gazette the codes that accompany each designated substances regulation.

2. The Analytical Process

In reviewing the analytical process employed to develop a standard for mercury, council's role is to judge how effectively the ministry has assembled, reviewed and analysed the available evidence in relation to the final conclusions reached. In embarking on this task, council has the advantage of examining a complex and difficult process in its final stage. Hence, council is in a position to review not only the arguments put forward by participants, but also the rationale supplied by the ministry for formulating its regulation in a particular fashion in light of the evidence and arguments raised.

As a first step in discharging its responsibilities, members of council's Task Force on Regulations met with ministry officials to seek more complete information on the rationale employed by the ministry to arrive at several important regulatory decisions. The key analytical issues taken up with ministry staff are discussed below.

a) *The Rationale for the Choice of Control Levels Contained in the Mercury Regulation and in the Code for Medical Surveillance for Mercury*

In its interim letter of August 27, council raised two points pertaining to the choice of airborne and biological control levels for exposure to elemental mercury (hereinafter referred to as mercury). First, council wished to know why the contents of a recent World Health Organization (WHO) report,[2] which considered the question of appropriate control levels for mercury and mercury compounds, had not been discussed in the ministry's background materials. Second, council inquired into the ministry's rationale for increasing the urine mercury removal level presently contained in the Code for Medical Surveillance for Mercury, from 0.15 mg/L to 0.25 mg/L.

In response to the first point, the minister's letter stated that, although a discussion of the WHO document was not included in the background materials, ministry staff had, nonetheless, reviewed the contents of the report in a thorough fashion. Essentially, the ministry chose not to follow the recommendations contained in the WHO report, which advocated more stringent control levels than those ultimately adopted in the regulation, for the following two reasons. First, the WHO recommendations were based on studies that the ministry had already evaluated. Second, the control levels advocated by the WHO study group were formulated, in part, on the basis of a study conducted by Buchet *et al*,[3] which indicated that certain biological effects occur in the kidney following exposure to low levels of mercury. The ministry concluded, however, that since the significance of these results had yet to be determined, it would not be appropriate to reduce the 0.05 mg/m^3 Time Weighted Average Exposure Limit (TWAEL) specified in the regulation to the 0.025 mg/m^3 level recommended in the WHO report.

Council recognizes that, in the process of selecting control levels for designated substances, several complex issues must be addressed. One such issue involves a determination of the degree of weight to be accorded to studies that indicate that exposure to a particular substance produces biological effects, which may or may not indicate a deterioration in health. The options are to take these effects into account in setting control levels or to discount these results until such time as their significance can be better understood. Council notes that, in respect to the results of the Buchet study, the ministry has chosen to adopt the second approach. Whichever approach is thought to be desirable, however, council believes that the ministry's choice of an appropriate airborne mercury exposure level was arrived at only after a complete evaluation of the scientific literature. While on this point, council wishes to note that its interpretation of the recommendations contained in the NIOSH criteria document on mercury[4] differ somewhat from the interpretation provided in the minister's letter of November 16.

A related issue addressed by council in its letter of August 27, concerned the ministry's rationale for increasing the urine mercury removal level from 0.15mg/L to 0.25/L. This decision was made on the basis of test results reported in a study conducted by Langolf *et al*[5]. The Langolf study examined workers employed in chloralkali plants for several manifestations of mercury toxicity (tremor, neuro-muscular effects, etc.). The paper concluded that, given proper hygiene practices, workers with a group average urine mercury level of 0.24 mg/L should not develop 'functionally' significant behavioural effects. In its interim letter, council noted that there appeared to be a number of methodological shortcomings in the study that cast doubt on the weight to be placed on the conclusions reached. In response to council's concerns, the ministry conducted a thorough reassessment of the scientific literature. On the basis of this review, the ministry concluded that there was some uncertainty of whether a 0.25 mg/L urine mercury removal level would provide an adequate degree of protection for all workers. The ministry, therefore, took the view that it would be prudent to lower the urine mercury removal level from 0.25 mg/L to 0.20 mg/L. In council's opinion, the ministry, in arriving at the final removal level, has reviewed and analysed the available scientific evidence in a thorough manner.

Council is also pleased to note that concentrations of mercury in urine will now be measured in relation to creatinine excretion. This method of sampling will improve the accuracy of test results by controlling for fluctuations in mercury excretion that occur during the course of a day. Council is also cognizant of the amendment made to section 4(1) (a) (i) of the Code for Medical Surveillance for Mercury, which now prescribes that only one urine mercury test result between 0.15 and 0.20 mg/L will be sufficient to cause a review to be made of a worker's health status, personal hygiene and work practices.

b) *The Teratogenic Effects of Mercury*

In the ministry's background materials, evidence is presented to suggest that, if a pregnant woman is exposed to mercury vapour, there is a risk that the fetus could be damaged by mercury accumulating in its tissues. Council wondered, therefore, why the Code for Medical Surveillance for Mercury, did not specify a lower biological removal level for women capable of bearing children. This strategy, council noted, was incorporated in the Code for Medical Surveillance for Lead. In response to this point, the ministry stated that adequate scientific information does not exist on the effects produced in small children as a result of chronic, low level exposures to mercury. As a result, a different biological removal level could not be specified for women capable of bearing children. Instead, the Code for Medical Surveillance for Mercury contains a cautionary note to the effect that 'exposure of females capable of bearing children should be kept to a minimum.' On the basis of the explanation provided, council believes that the decision to refrain from setting a lower biological removal level for women capable of bearing children was made on reasonable grounds.

Council would, however, like to make two additional comments on this subject. First, since the Code for Medical Surveillance for Mercury states that exposure of females capable of bearing children should be kept to a minimum, there is the possibility that some employers might equate minimal exposure with no exposure. Should that occur, women capable of bearing children could be excluded from certain worksites where mercury is present. Council recognizes that problems of discrimination could also arise when different biological removal levels are set for women capable of bearing children, on the one hand, and for all other workers, on the other. Council hopes to provide some advice to the ministry on this complex issue when its Task Force on Women and Occupational Health and Safety completes its deliberations.

Council's second comment concerns the ministry's regulatory strategy in respect to alkyl mercury compounds. Council wonders if the ministry has given appropriate consideration to the teratogenic effects of alkyl mercury compounds on the developing fetus and the option of restricting the exposure of females capable of bearing children to this highly toxic substance. In council's view, the difficult regulatory issues identified in this section underscore the need for the development of a general set of principles to deal with the exposure of females capable of bearing children to all toxic agents.

c) *The Economic Costs of Achieving Lower Control Levels*

In their meeting with ministry officials, members of council's Task Force on Regulations asked whether a further lowering of control levels would impose significant extra costs on industry. In response, ministry officials stated that, since control levels for mercury were selected on the basis of health effects data, a consideration of economic cost is not really relevant.

In Advisory Memorandum 81-I on lead, council indicated that an analysis of the economic costs that a proposed regulation is likely to impose on industry is necessary in order to answer the question of whether control levels could be lowered at relatively little cost to industry (where uncertainty exists about the health effects produced by a substance at specific levels of exposure). In this respect, council welcomes the suggestion made by Dr. Ann Robinson that council and the ministry enter into further dialogue and discussion on the appropriate role for economic analysis in the standard setting process.

d) *The Decision to Calculate Time Weighted Average Exposure Limits Over a 40-Hour Sampling Period*

In its interim letter, council questioned the appropriateness of calculating TWAELs on the basis of a 40-hour sampling period, rather than over the customary 8-hour period. Council was concerned that the calculation of TWAELs over a 40-hour sampling period permitted workers to be exposed to concentrations of airborne mercury well above the 0.05 mg/m^3 for several days during the week, provided that the workers were removed from mercury exposure environments on other days of the week. If TWAELs were calculated over an 8-hour sampling period, on the other hand, the maximum exposure to which a worker could be subjected during the course of a given working day would be decreased substantially. In response to this point, ministry officials informed members of the task force that, because of the manner in which the body metabolizes mercury, it does not matter, from the point of view of a worker's health, whether a worker's weekly exposure to mercury is reached in two days or is spread over five days. In respect to the regulation of mercury, council accepts the ministry's statement that the calculation of TWAELs based on a 40-hour sampling period will not adversely affect the health of workers. However, council wishes to emphasize that a sampling period of 40 hours may not be appropriate for the measurement of worker exposure to other substances.

e) *The Decision to Exempt Dentists and Dental Personnel from the Application of the Regulation*

In its interim letter of August 27, council asked the ministry to explain the basis for its decision to exclude dentists and dental personnel from the application of the regulation. In the minister's letter of November 16, it is stated that dental offices were exempted from the regulation for essentially three reasons:

i) the health risk to dentists and dental personnel in Ontario, as a result of exposure to mercury, is minimal,
ii) the structure and requirements of the mercury regulation are not easily adapted to the dental office setting, and
iii) dentists and dental personnel are committed to working with the ministry to develop appropriate mechanisms for the control of health hazards in the dental office.

The letter also indicates that the provisions of the *Health Disciplines Act* are being reviewed to determine whether that statute might be utilized to assist in the control of toxic substances in the dental office environment.

Council recognizes that all workplaces are distinct in one sense or another. In this respect, various occupational groups could make the argument that, because of special circumstances, they should be exempted from the provisions contained in occupational health regulations. Council believes, however, that a harmful precedent would be set if the ministry acceded to this type of argument and, in the present case, permitted dentists and dental personnel to be exempted from the application of designated substances regulations.

Council also wishes to comment on the possibility that dental groups could be regulated under the *Health Disciplines Act*. The Report of the Ham commission emphasized the need to co-ordinate health and safety legislation under one ministry. The regulation of dental groups under a statute other than the *Occupational Health and Safety Act* could, in council's opinion, perpetuate the fragmentation that existed prior to the passage of this legislation. In light of these considerations, it is difficult for council to support a regulatory strategy to control workplace exposures in dental offices, except under the *Occupational Health and Safety Act*.

3. **The Legal-Technical Process**

In its review of the legal-technical aspect of the standard setting process, council is essentially interested in two questions. First, are the provisions contained in the regulation and codes internally consistent and, second, has the intent of the ministry been translated into legislation that is both clear and unambiguous?

Council's interim letter contained a number of points that pertained to the legal-technical process. From the letter of November 16, it is clear that ministry officials have given serious consideration to the points raised by council. In many instances, ministry officials have agreed with council's suggestions and, as a result, a number of changes were made both to the regulation and the accompanying codes. Among the new provisions added are the following:

i) the specification of preferred biological monitoring procedures for all forms of mercury,
ii) the specification of an 'action level' for review of work practices, health status and personal hygiene for workers exposed to alkyl mercury compounds,

iii) the stipulation that employers should maintain records on the frequency of use by workers of respiratory equipment, rather than the mere fact that such devices are being used, and

iv) the specification of action levels at which workers who had previously been removed from mercury exposure environments will be permitted to return to work.

In its interim letter, council also noted that, should the ministry consider it appropriate to release the results of biological monitoring procedures to joint health and safety committees, the results of blood mercury testing, in addition to urine mercury testing, should be provided. Council is pleased to note that the ministry has acted on this suggestion.

Council wishes to make several additional comments in respect to the legal-technical process. Council believes that the following points require further discussion, clarification, or comment:

a) *Does a Ministry Inspector Have the Authority to Order an Employer to Conduct a Workplace Assessment When the Employer Claims That the Regulation Does Not Apply to His Workplace?*

During their meeting with ministry officials, members of the Task Force on Regulations asked whether a ministry inspector could order an employer to conduct a workplace assessment when the employer claimed, in bad faith, that the regulation did not apply to his workplace. An employer could conceivably take this position on the basis that i) mercury was neither present, produced, processed, used, handled nor stored on the premises, or ii) that workers were not likely to inhale, ingest or absorb mercury. In response to this query, the ministry stated that section 145 of O. Reg. 658/79 (the regulation for industrial establishments) could be utilized to compel an employer to conduct a workplace assessment. Section 145 requires an employer to take all measures necessary to prevent exposure to any toxic substance by inhalation, ingestion or skin contact where the substance is either used or produced in a workplace. It was also noted that, by virtue of section 14(2) (g) of the *Occupational Health and Safety Act*, an employer is required to take every precaution reasonable in the circumstances for the protection of a worker. On the basis of these two provisions, ministry officials concluded that an inspector would have the authority to order an employer to conduct a workplace assessment. While council is satisfied with the explanation provided, it wishes to note that a provision similar to section 145 of the industrial regulation is not contained in O. Reg.660/79 (the regulation for mines and mining plants).

b) *The Application of the Regulation to 'On-Site' Construction Workers*

Section 3(2) of the mercury regulation provides that every employer to whom the regulation applies shall comply with sections 4 and 5 of the regulation in respect to all workers who perform construction tasks in the employer's workplace, irrespective of whether these construction workers are the actual employees of the employer. Sections 4 and 5 deal respectively with the maintenance of exposure limits and the use of personal protective equipment. In its interim letter, council asked whether the proposed construction regulation would provide these construction workers with additional protection against the adverse effects of mercury exposure (e.g. through the requirement for a health surveillance program). During the September 4 meeting, ministry officials stated that, while the format of the proposed construction regulation had not yet been finalized, it was envisaged that this regulation would provide some additional protection for this category of workers. Council recognizes that the development of occupational health regulations in the construction field is a complex task. Council also shares the ministry's view that the health of construction workers must be protected by regulation and hopes that this matter can be addressed as quickly as possible.

c) *The Authority of a Ministry Inspector to Determine Whether Respiratory Equipment May be Provided under Section 5(1) of the Mercury Regulation*

In its interim letter, council asked whether representatives from labour or management had the right to call in a ministry inspector in those situations where there was disagreement on whether respiratory equipment should be provided under section 5(1) of the regulation. Council wished to know, further, whether an inspector could issue an order to the effect that it was not proper to provide respiratory equipment in a particular situation. From the text of the November 16 letter, council takes it that the answer to both questions is 'yes' and that an inspector's 'decision' constitutes an order.

d) *The Further Assessment Required Under Section 8 of the Regulation*

In its interim letter, council asked the ministry why it had taken the position that the further workplace assessment, required under section 8 of the regulation, should be conducted subsequent to, rather than before, the occurrence of a change in the use, handling, processing or storage of mercury. In response to this question, the November 16 letter states that, in many instances, employers will be able to estimate changes in exposure at the planning stage. However, since a precise evaluation of these exposures cannot be made until a change in a work process has actually occurred, the 'final assessment' must be made at this stage. Council is pleased to note that ministry officials will help employers to anticipate potential sources of mercury exposure during the ministry's predevelopment review of engineering plans.

e) *Mandatory Removal of Workers*

A further point raised in council's interim letter bore on the question of whether an employer was obliged to remove a worker from a mercury exposure environment upon being informed by a physician that the worker was either fit with limitations or unfit to work with mercury. In response to this question, your letter states that the phrase 'who shall act thereon', contained in section 16(1) of the regulation, imposes a duty on an employer not to ignore the advice of a physician in respect to the subject of worker removal. Council believes, however, that the intent of section 16(1) could be expressed more clearly in order to ensure that an employer must remove a worker upon being advised to do so by a physician.

CONCLUSION

In Advisory Memorandum 81-I, council observed that the development of occupational health regulations is a difficult and complex task, especially in the context of an open consultative process. Council also stated that, with time, all parties involved in the standard setting process would be able to make more effective contributions to maximize the quality of occupational health regulations.

In reviewing the process by which the ministry has developed the mercury regulation, council wishes to note that the open consultative process pursued by the ministry with members of the public has caused significant beneficial changes to be made to the regulation. Council also appreciates the open attitude taken by ministry officials in respect to the points raised by council and the rigorous manner in which they have analysed a variety of complicated issues. It is evident, in council's opinion, that the consultative process, though time consuming, has contributed to the development of more effective occupational health regulations.

Footnotes

1. These suggestions are set out in Advisory Memorandum 81-I, which appears earlier in this annual report.
2. World Health Organization, Recommended Health-Based Limits in Occupational Exposure to Heavy Metals, Report of a WHO Study Group, Technical Report Series 647 (Geneva, Switzerland, 1980).
3. J.P. Buchet *et al*, Relationship Between Exposure to Heavy Metals and Prevalence of Renal Dysfunction. In: Archives of Toxicology (in press)
4. NIOSH, Criteria for a Recommended Standard . . . Occupational Exposure to Inorganic Mercury. 1973; p. 79.
5. G.D. Langolf *et al*, Evaluation of Workers Exposed to Elemental Mercury using Quantatative Tests of Tremor and Neuromuscular Functions. In: American Industrial Hygiene Association Journal; volume 39, December 1978; p. 983.

APPENDIX I

Ontario
Advisory Council on
Occupational Health &
Occupational Safety

Office
of the
Chairman

400 University Avenue
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416/965-2446

27 August, 1981

The Hon. Robert G. Elgie, M.D.,
Minister of Labour,
400 University Avenue,
14th Floor,
Toronto, Ontario.
M7A 1T7

Dear Dr. Elgie:

Re. Designated Substances Regulation on Mercury

Thank you for forwarding to us the proposed mercury regulation, along with the accompanying background material.

As was the case with council's review of the lead regulation, our review of the mercury regulation will deal with the consultative process, the analytical process and the legal-technical process employed by the ministry to develop its regulations. Council will, as in the past, submit its reply in two stages. This initial letter is designed to set out a number of issues which council would like to discuss with ministry staff, for purposes of clarification. Council will then submit a formal advisory memorandum based on a review of the final version of the mercury regulation.

In this regard, it would be helpful to have members of The Task Force on Regulations meet with your officials to clarify a number of points, the most important of which are listed below:

1. The Consultative Process

Our comments in this area are very similar to those which we have expressed in relation to the lead regulation. We recognize the special circumstances surrounding the publication of the first seven proposed regulations and the difficulty of adhering strictly to the procedures proposed by council in Advisory Memorandum 78-II. In this respect, council notes that the minister has undertaken, in his reply to Advisory Memorandum 81-I on lead, to give serious consideration to incorporating several new components into the consultative process for the development of regulations. For its part, council intends to review the recommendations set forth in Advisory Memorandum 78-II which dealt with the policy and process for developing regulations, to determine whether the procedures specified by council need to be modified.

2. The Analytical Process

Of concern to council's task force and council itself is the outcome of the analytical process. As stated in Advisory Memorandum 81-I, it is not council's role to pass judgment on the final values selected by government. But council is concerned about whether the evidence appears to have been assembled, reviewed and analyzed in a manner which is compatible with the final conclusions reached. In order to facilitate council's task in this area, we would like to discuss the following points with your ministry staff:

a) World Health Organization Recommended Standards for Exposure to Mercury

Although referenced, the ministry's background material omits any discussion of a recent report prepared by the World Health Organization entitled Recommended Health Based Limits in Occupational Exposure to Heavy Metals, Technical Report Series 647, 1980. This report recommends a time-weighted average exposure limit for mercury of 0.025 mg/m^3 (one-half the level chosen by the ministry) and a safe urine mercury level per gram of creatine of .05 mg/L (over four times lower than the urine mercury removal level selected by the ministry).

In endeavouring to develop safe control levels for exposure to harmful substances, one comes up against the problem of risk assessment. In the case of mercury, where high quality epidemiological data from human studies are not available, one must look to the strength and consistency of the epidemiological data that do exist and relate this information to available biological data, including the results of animal experiments. Since the WHO document, referred to above, utilizes this approach in arriving at appropriate control levels, it would be of value to council if the ministry could state more clearly why, in its final weighing of the biological and epidemiological evidence, it came to higher levels than those recommended by the World Health Organization. Since there is no discussion of the WHO document in the ministry's background material, it is difficult for council to form a judgment on this point.

b) The Decision to Increase the Urine Mercury Removal Level for Workers

Section 5(2) of the August, 1980 version of the mercury regulation specified that an employer was required to remove a worker from a mercury exposure environment, when the worker's urine mercury level exceeded 0.15 mg/L. This removal level was increased to 0.25 mg/L when section 5(2) was transferred to section 4(1)(a)(i) of the Code for Medical Surveillance of Mercury Exposed Workers. The increase appears to be based on two considerations: a) a study by Langolf et al which concludes that, given proper hygiene practices, workers with a group average urine mercury level of 0.24 mg/L should not develop "functionally" significant effects, and b) an in-house report from CIL which states that the company has not recorded any "significant signs or symptoms" associated with exposure to inorganic mercury while operating at levels up to and including 0.50 mg/L.

The Langolf study, cited above, examined chloralkali plant workers for several manifestations of mercury toxicity (tremor, neuro-muscular effects, etc.). A review of the Langolf study sugggests that the test results contained therein must be interpreted with some caution. That is so because the sample population consisted entirely of volunteers, the sample population was comparatively small and the study provides no data on the long term exposure histories of the workers who participated in the study. In addition, the Langolf study did not deal with other biological effects associated with low levels of exposure to mercury. In view of these points and considering the weight that the ministry has apparently placed on the Langolf study, council would appreciate a discussion on the relative weights accorded to different studies, taking into account the quality of the evidence presented.

An additional argument put forward by some companies in support of the proposition that the 0.15 mg/L urine mercury removal level should be raised was that this removal level was economically impractical. Is there evidence that adherence to the 0.15 mg/L removal level would impose significant extra costs on industry?

The ministry's uncertainty about the desirability of adopting lower control levels is set out on page H.36 of the background material, where it is stated that "In view of this possibility [i.e. that health effects can be substantiated at urine mercury levels below 0.25 mg/L] it might be prudent to indicate to industry the importance of working toward lower workplace concentrations in the future". If the objective of the ministry is to adopt exposure levels initially on the basis of health considerations (as indicated in the minister's letter to council dated August 11, 1981), and given the ministry's belief that industries should be working towards lowering levels of exposure, council would like to hear reasons for the decision to increase the urine mercury removal level.

c) The Teratogenic Effects of Mercury

In the background material supplied by the ministry, it is stated that where a pregnant worker is exposed to mercury vapour, there is the possibility that the fetus could be damaged by mercury accumulating in its tissues. This concern is reflected in section 5 of the Code for Surveillance of Mercury Exposed Workers which specifies that "exposure to females of child-bearing age should be kept to a minimum". Unlike the Code for Medical Surveillance for Lead, however, the mercury code does not set out a lower biological removal level for women of child-bearing age. Council would be interested in knowing why, in the case of mercury, the developing fetus should not be given a degree of protection similar to that afforded to the fetus under the lead regulation.

d) The Exemption of Dental Offices from the Ambit of the Regulation

In the background material, the only reasons advanced for the exclusion of dental offices from the application of the regulation are those contained in a brief submitted by The Royal College of Dentists of Ontario on behalf of itself and other organizations. Council would appreciate a discussion of the ministry's reasons for exempting dental offices and the strategy it plans to advance to ensure that dental personnel are protected from the adverse effects of mercury exposure.

e) Small Businesses

In its background material, the ministry states that the greatest potential for mercury exposure in Ontario may exist in thousands of small workplaces, such as instrument repair shops or dentists' offices. With the exception of the brief received from The Royal College of Dentists of Ontario, however, it is unclear whether the ministry solicited or received comments from small businesses with regards to the regulation of mercury.

3. The Legal-Technical Process

In its review of the lead regulation, council made a number of comments on the legal-technical aspect of the regulatory process. The majority of these comments apply with equal force to our review of the mercury regulation. In council's view, the following additional points need to be raised in the case of mercury:

a) The Application of the Regulation to "On-site" Construction Workers

According to section 3(2) of the draft of the mercury regulation submitted to council, sections 4 and 5 of the mercury regulation will apply to "on-site" construction workers employed at work places where mercury is present, etc. Is council correct in assuming that the proposed construction regulation will provide additional protection to these on-site workers, e.g. through the requirement for a workplace assessment and a health surveillance program?

b) The Time-Weighted Average Exposure Limit Based on a 40 Hour Work Week

Council has a concern about the use of a 40 hour base for the calculation of the time-weighted average exposure limit for mercury. It must be recognized that when the 40 hour base is utilized the maximum daily exposure to which a worker could be exposed may be significantly higher than would be the case if an 8 hour base were employed. For example, with the TWAEL of 0.05 mg/m^3 and the STEL of 0.15 mg/m^3 as specified in section 4(1) of the mercury regulation, a worker could theoretically be exposed to an average airborne mercury level just below 0.15 mg/m^3 during a full 8 hour working day, without exceeding the 40 hour TWAEL. This assumes that the worker would be removed from a high mercury exposure environment on other days of the week. If the TWAEL were based on an 8 hour figure, however, the highest average airborne mercury level to which a worker could legally be exposed, for any given 8 hour day, would be 0.05 mg/m^3. Council would, therefore, appreciate clarification on the point of how one can ensure that the 40 hour TWAEL is not utilized to expose workers to high levels of exposure on particular days of the week.

c) The Role of the Inspector in Determining Whether Respiratory Equipment May Be Provided Under Section 5(1) of the Mercury Regulation

Council would like some clarification on the following point. If management and workers at a particular plant cannot agree on the question of whether respiratory equipment should be provided in a given situation, would either party have the right to call in an inspector to resolve the dispute?

d) The Further Assessment Required under Section 8 of the Mercury Regulation

One brief submitted to the ministry suggested that the further assessment specified under section 8 of the regulation (for those situations where a change has been made to a process involving mercury, etc. that could result in a significant difference in worker exposure to mercury) should occur before such changes are made, rather than afterwards. Council would have been interested in the ministry's reaction to this suggestion, since it is assumed that companies give consideration to levels of exposure before decisions are made to alter work processes.

e) Information Regarding the Use of Respirators

Section 14(1) of the draft of the mercury regulation submitted to council no longer requires that a worker's exposure records contain information on the dates and lengths of time that the worker used respiratory equipment. Now, it is only the use of respiratory equipment by the worker that must be recorded. Council can appreciate that the requirement that both length of use and the actual dates of use be recorded could produce an administrative burden for some employers. A compromise might be to mandate that frequency of use of respiratory equipment (possibly calculated in terms of the number of working days per year that a worker used his respirator) be recorded. Information of this sort could be useful in epidemiological research, whereas the mere fact that a worker used respiratory equipment would be less useful.

f) The Medical Information Provided to the Joint Health and Safety Committee

Council would like clarification on the question of why a joint health and safety committee is entitled to receive the results of urine mercury monitoring (the favored test to measure exposure to inorganic mercury compounds) but not the results of blood mercury monitoring (the preferred test for measuring exposure to alkyl mercury compounds).

g) Return to a Mercury Work Area

Council notes that, unlike sections 4(1)(a)(i) and (ii) of the Code for Medical Surveillance for Lead, the same sections of the Code for Medical Surveillance of Mercury Exposed Workers contain no indiction of when a worker who has been removed from a mercury exposure environment, may be permitted to return to work. Council is interested in the ministry's reasons for treating the two substances differently.

h) Mandatory Removal of Workers

Council would like clarification on what is meant by the phrase "who shall act thereon" which is contained in section 16(1) of the draft of the mercury regulation submitted to council.

i) Contents of the Code for Medical Surveillance of Mercury Exposed Workers

Council would appreciate clarification on the following points as they relate to the medical surveillance code for mercury:

i) why are favoured clinical tests specified for inorganic and alkyl mercury compounds, but not for organic mercury compounds other than alkyl mercury compounds, and

ii) why is an action level for "a review of work practices and personal hygiene" specified for workers exposed to inorganic mercury compounds but not for workers exposed to alkyl mercury compounds?

Council is grateful for the opportunity to comment on the mercury regulation in two stages. This approach permits council to gain a fuller understanding of the rationale surrounding different aspects of the regulation. As in the case of the lead regulation, council assumes that it will receive the mercury regulation in its final form, so that a formal advisory memorandum on the regulation can be submitted.

Yours truly,

Dr. J. F. Mustard

APPENDIX II

Office of the Minister

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November 16, 1981

J. Fraser Mustard, M.D.,
Chairman
Advisory Council on Occupational
Health and Occupational Safety
400 University Avenue, 15th Flr.
Toronto, Ontario

Dear Dr. Mustard:

Thank you for your letter of August 27, 1981, concerning the mercury regulation. As you know, on September 4, Dr. Robinson and her staff met with Council members to discuss the issues raised in your letter. To further our mutual understanding and resolution of the issues, I believe I should set out the Ministry's position.

As Mr. Armstrong stated at his meeting with the Council on October 13, 1981, the Ministry will make available to Council members the final regulation, subject to any changes which could emerge as a result of the Council's own advice. I attach the final mercury regulation, and the referenced codes which have been amended following consideration of some of the issues raised by the Council members.

I note that the Council would like to review the consultative process used by the Ministry in developing further designated substance regulations, after the review of current proposed regulations has been completed. I look forward to receiving this advice and you may expect full and continuing co-operation from Dr. Ann Robinson and her staff. The Ministry remains committed to an open and meaningful consultative process.

You have raised several matters relating to whether the Ministry has reached reasoned conclusions based upon the evidence it has assembled and received. They are:

a. World Health Organization recommended standard for exposure to mercury.

b. the decision to change the urine mercury level at which workers would be removed from further exposure.

c. the teratogenic effects of mercury.

d. the exemption of dental offices from the ambit of the regulation.

e. small business.

I shall discuss these issues in order.

(a) World Health Organization

Your first issue concerns the report prepared by the World Health Organization entitled, Recommended Health Based Limits for Occupational Exposure to Heavy Metals, Technical Report Series 647, 1980 in which an exposure limit of 0.025 milligrams of mercury per cubic metre of air is suggested. While the Ministry did not include a detailed analysis of the report and its findings in the original health effects report on mercury prepared by the Special Studies and Services Branch in 1978, the staff specialists continued to review the scientific literature. In 1980, the World Health Organization report was referenced in the addendum to the mercury health effects report.

In reviewing the document the Ministry found that it did not contain references to any studies not already considered by the Ministry in its own report on the health effects of mercury. Indeed, on a close examination of the World Health Organization study it appears that they rely upon the same epidemiological study of R. G. Smith (1970) which led the Ministry to recommend an exposure limit of 0.05 mg of mercury per cubic metre of air. Smith did not report any significant health effects in workers exposed to below 0.1 mg of mercury per cubic metre of air.

The World Health Organization also relied upon some recent experimental studies which indicated that there were biological changes occurring in the kidneys. The Ministry reviewed this work in which the authors (Buchet et al 1980) suggested that the measurement of specific molecular weight proteins and of B-galactosidase activity in urine allows an earlier detection of kidney dysfunction than does the determination of total protein. However, in the same paper the authors stated that they could not explain the significance of these changes for the health of workers exposed to mercury.

As reported at the September 4th meeting, the Ministry has conferred with a number of experts to determine their understanding of the implications of these findings. They confirmed the conclusion that, until more research is conducted, the precise significance of Buchet's work could not be determined. Thus, the Ministry concluded that the exposure limit of 0.05 mg mercury per cubic metre of air was still appropriate. I am advised that the task force which met with the Ministry on September 4 appeared to be satisfied with the report of the Ministry's analysis with particular reference to the W.H.O. report.

(b) The Decision of Change the Criterion for Removal from Exposure

Section 5(2) of the August, 1980 version of the mercury regulation specified that an employer was required to remove, from a mercury exposure environment, a worker whose urine mercury concentration exceeded 0.15 mg/L. The revised regulation does not contain this provision, but the Code for Medical Surveillance of Mercury Exposed Workers stipulates that workers with urine mercury concentrations between 0.15 and 0.25 mg/L should be carefully watched by the physician and the employer, and that workers with mercury concentrations above 0.25 mg/L should be removed from exposure.

As a result of your letter and the meeting on September 4th, the Ministry has carefully re-examined its position. I am advised:

> The study used to establish the occupational exposure limit of 0.05 mg/m^3 for mercury in air, a value used throughout the world, is the study made by R. G. Smith of 567 workers exposed to mercury vapour at 21 chlor-alkali plants in Canada and the United States.
>
> At all the work places included in the study, standard methods were used to calibrate the instruments used to determine the time-weighted average mercury concentrations in air. Also medical examination of the workers was done according to a standard procedure. The length of exposure to mercury was taken to be one study year, and the findings for the 567 workers were compared with those of a control group of 313 unexposed workers.
>
> The time-weighted average mercury concentrations in air were found to range between 0.01 and 0.27 mg/m^3. About 85% of the workers were exposed to time-weighted average concentrations of less than 0.10 mg/m^3. The workers were divided into five groups based on exposure.
>
> The study found that workers exposed to levels of mercury in air in the range of 0.24-0.27 mg/m^3, showed symptoms consistent with early mercury intoxication, such as tremor, nervousness and insomnia. There is also a significant increase in these symptoms in the group exposed to airborne mercury concentrations of 0.11 to 0.14 mg/m^3. Smith therefore concluded that only workers exposed to mercury levels greater than 0.10 mg/m^3 are at risk of developing signs of mercury intoxication, as workers exposed to mercury concentrations below this level differ little from the control group. In 1973, on the basis of Smith's

findings, the U.S. National Institute for Occupational Safety and Health (NIOSH) proposed a time-weighted exposure limit for mercury in air of 0.05 mg/m^3, as this figure would provide a good margin of safety for most workers.

The average level of mercury in the urine of unexposed persons is less than 0.020 mg/L. The level of mercury in exposed workers is often much higher than this but care is need in attributing significance to such results.

Mercury tends to accumulate in the kidney and is not excreted in the urine as quickly as it is removed from the blood. The following difficulties have been observed with respect to interpretation of urine mercury levels:

- There is a better correlation between mercury concentrations in air and mercury concentrations in urine when you consider groups of exposed workers than when you consider individual worker's values.
- The amount of mercury excreted by an individual worker may fluctuate during the day, and may vary from day to day particularly when expressed as the concentration of mercury in urine.
- Mercury excretion may continue for weeks or months even after the worker is removed from mercury exposure.
- Some workers may show symptoms of mercury-poisoning even though their mercury urine levels are low; some workers with high levels will not have symptoms of poisoning.

Smith's study found good linear correlation between air and urine mercury levels in groups of workers at air mercury levels of 0.01 - 0.27 mg/m^3, using the average urine level for the study year for each worker. These findings were confirmed in 1979 by Scandinavian researchers who studied two groups of chlor-alkali workers exposed to air mercury levels of 0.064 and 0.023 mg/m^3.

The correlations between urine-mercury levels versus air mercury levels indicates a urine mercury level of 0.10 - 0.15 mg/L corresponds to an exposure limit of 0.05 mg/m^3 and a urine mercury concentration of 0.25 mg/L corresponds to an airborne concentration of 0.1 mg/m^3.

There is another body of evidence which suggests that no functionally significant effects were found in mercury exposed workers subjected to proper hygiene controls who had an average mercury level of 0.24 mg/L. The work by Langolf indicates that the first subclinical effects were observed in cases where the urinary mercury levels had exceeded 0.5 mg/L more than once during the previous year. Furthermore, Schuckmann (1979) conducted a study on 39 chlor-alkali workers exposed to airborne concentrations of mercury of less than 0.1 mg/m^3 for more than seven years at two plants in Frankfurt, Germany. Because mercury affects the central nervous system, he sought to quantify the early adverse health effects of mercury exposure by using various psychomotor tests. He found no difference between the clor-alkali workers and a non-exposed control group. Thus the upper urine mercury limit which would protect most workers is around the order of 0.25 mg Hg/L.

Despite the above findings there have been reports of cases of workers with signs of mercury poisoning who have been exposed to airborne concentrations between 0.05 and 0.10 mg/m^3.

- In the late 1940's, A R. Smith et.al. reported that 14 out of 35 hatters had symptoms of mecury intoxication even though mercury in air levels were below 0.10 mg/m^3.
- In 1950, in her studies of workers engaged in the repair of direct current meters, Bidstrup found symptoms of mercury intoxication in one of sixteen workers, exposed to a level of 0.005 - 0.06 mg/m^3. The worker had been exposed to mercury for 19 years.
- In 1955, Turrian et.al. studied 58 factory workers exposed to levels of mercury vapour ranging from 0.01 to 0.60 mg/m^3. In a group of 26 workers exposed to levels of mercury vapour between 0.01 and 0.06 mg/m^3, five workers exhibited tremor and two showed signs of erethism.

In the latter two reports there is a lack of information on the long term exposure histories of workers in these earlier studies. Despite this weakness and taking into account the recent work of Buchet on kidney damage considered in section (a), there is sufficient doubt cast to lead the Ministry to believe that the mercury in urine concentration should be reduced to 0.20 mg Hg/L.

On the basis of this above advice, I believe it is reasonable to amend the Code of Medical Surveillance to require the removal of workers with confirmed urine mercury concentrations exceeding 0.20 mg/L. The existing provisions in the Code require the physician and employer to monitor the health status of all workers with mercury urine concentrations of 0.15 mg/L, and investigate the circumstances giving rise to these test results. Indeed, the physician is bound to advise the employer to remove any worker whose health has been affected by exposure to mercury despite the urine mercury concentration.

(c) The teratogenic effects of mercury

In your letter you express concern that the Code of Medical Surveillance for Mercury exposed workers notes that exposure of females of child-bearing age should be kept to a minimum but does not include a lower removal level for women capable of bearing children. The Ministry has reviewed the evidence available which indicates that mercury can cross the placenta. As you know, mercury affects the central nervous system. However, there is no information on the effects of chronic low doses of mercury on small children which would permit a limit to be set to provide protection for the fetus. The World Health Organization report on mercury, noted in section (a), included the suggestion that the exposure level should be as low as possible. At this time it is reasonable to include a cautionary note in the education section of the Code of Medical Surveillance. This cautionary note may be likened to the traditional warning issued by pharmaceutical manufacturers when they advise physicians that a particular drug should not be prescribed when other incompatible drugs are being taken by a patient.

In light of the existing situation the Ministry will continue to review the emerging literature. If our analysis of any evidence indicates that this position should be changed, the regulation will be amended accordingly.

Please note that the wording of the Code has been amended to refer to women capable of bearing children rather than women of child-bearing age.

(d) Exemption of Dental Offices

In your letter of August 26, you imply that the Ministry consulted only with representatives of the Royal College of Dentists of Ontario in reaching this decision. As noted in the background material submitted along with the proposed regulation, the Ministry consulted with the associations/organizations representing employers and workers in the dental community. The representatives were concerned that while the mercury regulation was appropriate for an industrial setting, it would not be effective in a dental office. After careful consideration dental offices were exempted from the regulation because:

1. the published literature and recent studies of the dental setting in Ontario indicate that the risk to health from exposure mercury is minimal. However, further investigations will be undertaken to confirm this observation.

2. the structure and requirements of the mercury regulation are suited to control the mercury hazard as it occurs in industrial establishments and is not easily adapted to the office setting. For example the procedure for employee involvement in the initial assessment, the development of control programs, and the mandatory establishment of joint health and safety committees would be difficult to apply in the typical dental office with a dentist, dental assistant and secretary; and

3. the dentists and representatives of the dental hygienists and technicians are committed to working with the Ministry in developing a control mechanism for health hazards in dental offices.

As a result, the decision to exclude dental offices and recognize the possible need for other control measures in the dental sector, the Ministry is undertaking a study of toxic substances including mercury, used in dental practices and workers exposure thereto.

At the same time, the provisions of the Health Disciplines Act will be reviewed to determine its bearing in any strategy to control chemical substances in dental practices.

(e) Small Business

The Ministry has not received any specific submissions on the mercury regulation from representatives of small business. There was a general brief from the Canadian Federation of Independent Businesses which protested the need to regulate any toxic substances. However, several trade associations with membership drawn from a wide spectrum from the business community did submit briefs.

The Ministry is aware that the small business community may be reluctant to comment on the proposed regulations. The Ministry is working with the accident prevention associations and related trade associations to improve communications. Furthermore, I look forward to receiving the Council's advice on the need for financial incentives for small businesses which may require assistance in establishing an occupational health program.

You have raised a number of questions concerning what you have termed the 'legal-technical process'. They are:

(a) the application of the regulation to 'on-site' construction workers;

(b) the inclusion of a time-weighted average exposure limit based on a 40-hour week;

(c) the role of the inspector in determining whether respiratory equipment may be provided under section 5(1) of the mercury regulation;

(d) the further assessment required under section 8 of the mercury regulation;

(e) information regarding the use of respirators;

(f) the medical information provided to the joint health and safety committee;

(g) return to a mercury work area;

(h) mandatory removal of workers; and

(i) The Code of Medical Surveillance of mercury exposed workers.

I shall deal with these issues in order.

(a) The Application of the Regulation to 'On-site' Construction Workers

You have asked whether a regulation for mercury on construction projects will provide provisions similar to those in the mercury regulation, e.g., workplace assessment and health surveillance. As discussed at the September 4 meeting, the Ministry is presently preparing a model regulation to control specific toxic substances in the construction industry. The specific contents of this regulation are under study and have not been finalized. Once the appropriate provisions have been identified, the Ministry will consult with the affected parties. It is my intention that the health of construction workers will be protected by regulation.

(b) The Timeweighted Average Exposure Limit based on a 40-hour Sampling Period

As the Ministry indicated at the September 4th meeting the exposure limit of 0.05 with a maximum concentration of 0.15 mg Hg/m^3 of air was established to prevent damage to workers' health where long term exposures to low airborne concentrations of mercury are involved. The scientific basis for the exposure limit was derived from studies in which workers had been employed for many years in mercury exposed jobs.

In addition, chronic mercury poisoning is characterized by a slow accumulation of mercury in the body and it takes a long time (35 - 90 days) to reduce the build-up of mercury in tissue by one-half.

The regulation also provides for the continuing medical surveillance of workers exposed to mercury. The Code for Medical Surveillance calls for periodic urine mercury tests and stipulates that workers with mercury concentrations above 0.15 mg/L should be carefully observed and those with concentrations above 0.20 mg/L should be removed from work until the mercury concentration drops to 0.1 mg Hg/L.

In the above context the Ministry believes that the exposure limit for mercury should continue to be calculated on a 40-hour basis.

(c) Role of the Inspector in Determining whether Respiratory Equipment may be provided under section 5(1)

As your task force members noted at the September 4 meeting, the August 1980 version of the regulation indicated that respiratory equipment could be used with the approval of an inspector in certain circumstances only. Public comments pointed out the contradiction between the need to obtain an inspector's approval to use a respirator and the need for a provision permitting the use of respirators in emergencies. The Ministry acknowledge these weaknesses and amended section 5, as governed by section 4, to prohibit the use of respirators except in specific circumstances. If there is a dispute between management and labour on the use of respirators, either party can call upon the ministry inspectorate to judge the conditions and leave a decision. However, the revised provision removes the inspector from the initial decision-making process at the plant level and places him in a position to assist the parties when the need arises.

(d) Further Assessment required under section 8

When a change in the workplace could result in a significant difference in the exposure of workers to mercury, the employer is required to conduct a further assessment in consultation with the joint health and safety committee. In many instances, employers may be able to estimate the change at the planning stage or with Ministry assistance during the pre-development review of engineering drawings. However, the final assessment will need to be made with the changes in place.

(e) Information regarding the Use of Respirators

You noted that the Code for Respiratory Eqauipment for Mercury Exposed Workers did not require employers to record the frequency of use of a respirator by a worker. The Ministry agrees and has amended the Code. It is now in keeping with a similar requirement referenced in the respirator code of the Lead Regulation.

(f) Medical Information provided to the Joint Health and Safety Committee

The Ministry accepted your comment about providing to the joint health and safety committee on a confidential basis the results of blood tests to determine the extent of exposure to alkyl mercury compounds; sub-section 16(3) has been amended.

(g) Return to a Mercury Work Area

Council commented that there was no specific definition contained in the Code of Medical Surveillance of Mercury as to when a worker who had been removed from mercury exposure would be permited to return. A provision has been inserted in the Code requiring the urine mercury concentration to be below 0.1 mg/L before re-entry.

(h) Mandatory Removal of Workers

The Council members questioned what the clause "who shall act thereon" means in sub-section 1 of section 16. This provision was inserted to impose a duty on the employer to ensure that the advice of the physician in dealing with the removal of workers who may be "unfit" or "fit with limitations" for continued exposure to mercury was not ignored.

(i) Contents of the Code of Medical Surveillance

As a result of the September 4th meeting, changes have been made to the Code to include preferred medical tests for mercury and its compounds. There is, in addition, an action level for review of work practices and the health status of affected workers exposed to alkyl mercury compounds.

As will be evident from the length and detail of my reply, the Ministry has given serious consideration to your comments and suggestions which resulted in several changes in the Codes and one change in the regulation. I believe this process has resulted in a better regulation and commend Council members for their diligent efforts.

Yours truly,

Robert G. Elgie, M.D.
Minister

att:

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February 9, 1982

Dr. J. F. Mustard
Chairman
Advisory Council on Occupational
Health and Occupational Safety
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Toronto, Ontario
M7A 1T7

Dear Dr. Mustard:

I write to thank you for submitting Advisory Memorandum 81 - III concerning the mercury regulation. I am pleased to note that the Advisory Council has found the open consultative process used by the Ministry in developing the regulation to be effective. Moreover, your positive endorsement of the vigorous analysis of the scientific literature undertaken by Ministry officials is most reassuring.

You have raised several matters which require comment. These are:

1. The need to publish the codes adopted by reference in the mercury regulation in the Ontario Gazette.
2. The teratogenic effects of alkyl mercury.
3. The role of economic analysis in the regulation-making process.
4. The decision to calculate a time weighted average exposure limit over a 40-hour period.
5. The decision to exempt dentists and dental personnel from the application of the regulation.
6. The authority of a Ministry inspector vis-à-vis the application of the regulation.
7. The development of a mercury regulation for the construction industry.
8. The authority of a Ministry inspector vis-à-vis the use of respiratory equipment.
9. The wording of subsection (1) of section 16 of the regulation.

. . /2

I will respond to these issues in order.

1. The need to publish the codes adopted by reference in the mercury regulation in the Ontario Gazette.

The Council has put forward persuasive arguments in favour of publishing the codes which are referenced in the designated substance regulations, but are not published in the Ontario Gazette at the same time as the regulation itself. I would note that the codes are published with the regulation in booklet form once they become law. In addition, during the consultative process draft copies of the regulation and the codes have been distributed together to affected parties. These actions facilitate the open consultations undertaken by the Ministry.

Legal counsel, however, advises that it has been the custom and practice of Legislative Counsel and the Office of the Registrar of Regulations to publish the regulations without referenced materials and that the practice will continue until such time as the courts decide otherwise. In light of this position, the Ministry is unable to accede to Council's request.

2. Teratogenic effects of alkyl mercury

Council questioned whether the Ministry had given appropriate consideration to the teratogenic effects of alkyl mercury and whether the Ministry had considered restricting the exposure of females capable of bearing children to this toxic substance.

The teratogenic effects of alkyl mercury compounds were considered by the Ministry. In The Report on the Designation of Mercury in Ontario, dated July 1981, the effect of mercury on pregnancy is reviewed (pp 3.10 - 3.12) and particular attention is paid to alkyl mercury compounds. In addition, the "Health Criteria Document: Alkyl Mercury Compounds" (Addendum H No. 2) deals with the teratogenic effects of alkyl mercury. The available scientific literature indicates that alkyl mercury crosses the human placenta and since alkyl mercury affects the nervous system of the developing fetus, the Ministry recommended that employers should keep the exposure of female workers capable of bearing children to a minimum.

The teratogenic effects of alkyl mercury compounds was an important influence leading the Ministry to incorporate general advice to restrict exposure to mercury compounds in the Code for Medical Surveillance. Section 5 of the code deals with all types of mercury compounds, including alkyl mercury. It states that, "Exposure of females capable of bearing children should be kept to a minimum."

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The Council also raised the issue of potential discrimination against women arising in situations where employers fail to hire women because they equate the Ministry advice of minimal exposure of women capable of bearing children with no exposure to all forms of mercury. I look forward to receiving the Council's advice on this complex subject once its Task Force on Women and Occupational Health completes its work. However, I would advise you that the Ministry considered this issue and concluded that the advice in the Code of Medical Surveillance does not infringe on the right of women to equal treatment with respect to employment. There are circumstances where the right to equal treatment with respect to employment would not be infringed where the discrimination in employment because of sex, age, record of offences or marital status of the applicant is a reasonable and bona fide qualification because of the nature of the employment. This principle is set out in section 4 (6) of The Ontario Human Rights Code and will continue under section 23 (b) of the new Human Rights Code, 1981 which is awaiting proclamation.

The Ministry considered that the health of a fetus, which could be affected by exposure to a toxic substance required special protection under the mercury regulation. If employers acting on this advice limit employment opportunities resulting in charges of discrimination, there are remedies available under the Human Rights Code and each case will be dealt with on its merits. The Human Rights Commission has dealt with a similar situation in the past and has ruled that the protection of the health of a fetus is a reasonable and bona fide qualification for an employer to limit employment opportunities for women capable of bearing children. The Ministry is bound, legally and morally, to set out all reasonable measures to protect the health of workers exposed to known teratogenic substances in the course of regulating a toxic element like mercury.

3. The role of economic analysis in the regulation-making process

It is clear from the advice provided on both the lead and mercury regulations that the Advisory Council has a decidedly different view of the role of economic analysis in the regulation-making process. I am pleased to note that the Ministry and the Council will continue their dialogue on this matter and await, with interest, Council's advice on the use of scientific evidence and economic analysis in the development of regulations.

Until this advice has been received, the Ministry's policy on the role of economic analysis will remain unchanged. I believe my reply of August 11, 1981 to Advisory Memorandum 81 - I on the lead regulation summarized succinctly this position and it applies equally to the mercury regulation.

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I stated that:

> " The blood lead level of 0.70 mg/L and the airborne lead level of 0.15 mg lead per m^3 were selected on the basis of the best health evidence available to the Ministry. The reasons for the selection of these levels are detailed in my letter of June 3, 1981, (and attachments).
>
> Only after the Ministry had determined the appropriate exposure levels for blood and airborne lead on the basis of health effects evidence was the question of economic impact considered. As the document entitled "Assessing the Impact of Designated Substances Regulations" indicated, complex economic impact studies would be costly and time-consuming and may be justified only where an initial evaluation of the impact of the target levels indicate the likelihood of adverse consequences to affected users. As I have said earlier, in most instances I would hope that respondents would provide detailed material relating to the impact of the regulation on their operations following the publication of the proposed regulation, which the Ministry could then consider and analyze. In the view of the Ministry, levels should continue to be determined initially on the basis of health considerations. Moreover, I must say that I do not necessarily agree with the suggestion that levels lower than those justified on the basis of the best available health studies should be chosen simply because such levels could be achieved without imposing "significant additional economic costs". "

4. The decision to calculate a time weighted average exposure limit over a 40-hour period

I am pleased to acknowledge Council's acceptance of the rationale for a TWAEL for mercury based on a 40-hour sampling period. I have previously noted your concern about the appropriateness of applying a 40-hour TWAEL for all substances. As discussed at the September 4, 1981 meeting with Council, the decision to use a 40-hour TWAEL for the seven designated substances has been based on the need to protect against the chronic effects of accumulated exposure to these substances and to accommodate the increasing prevalence of novel work schedules in industry. It must be emphasized that 40-hour TWAEL's may be appropriate only for chronic hazards. Where the purpose of an exposure limit is to protect against more immediate effects of a substance, 8-hour TWAEL's may be necessary and, in some circumstances, a TWAEL based on an even shorter period of time may be appropriate. The best course of action, ultimately, may be to decide which type of TWAEL to set on a case-by-case basis, according to the toxic effects and mechanism of action of each substance being regulated.

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5. The decision to exempt dentists and dental personnel from the application of the regulation.

In your letter of August 26, 1981 and at the September 4, 1981 meeting with Ministry staff, the Council members questioned the decision to exempt the dentists and dental personnel from the regulation. On September 4 Ministry staff explained the reasoning behind this decision and this was summarized in my letter of November 16, 1981. My views have not altered. The exemption does not establish a harmful precedent, but rather indicates the Ministry's sensitivity to the structural differences in some activities where application of an industrial type of regulation is unrealistic.

As I noted on November 16, 1981, the Ministry intends to review the use of all chemical hazards in the dental community and, if necessary, to develop an appropriate regulation under The Occupational Health and Safety Act in consultation with the representatives of the dentists and dental personnel. A project specification has been developed to examine the exposure of workers to occupational health hazards that may occur in dental practices. This study will help to determine the nature and scope of any regulation necessary for the control of hazards in dental offices. It includes:

- a literature survey of potential hazards (including mercury, anesthetic gases and other hazards);
- a survey of current dental practices and evaluation of potential exposures;
- an evaluation of exposure to mercury in dental offices;
- contact with the concerned associations;
- review of the provisions of The Health Disciplines Act.

6. The authority of a Ministry inspector to order an employer to conduct a workplace assessment

The Council has raised the issue of the application of the regulation where an employer argues that mercury is not present, used, stored, or handled and worker exposure is not likely and therefore concludes an assessment is not necessary. I will first set out my reply to the same question raised in the context of the lead regulation. On August 11, 1981, I stated that:

> "With respect to the issue of an inspector's power to order an employer to conduct a workplace assessment, sections 3, 6, and 9 apply.

. . /6

> Section 3 (1) provides that the regulation "....
> applies to every employer at a workplace where lead is present, produces, used, handled or stored and at which a worker is likely to inhale, ingest or absorb lead." Section 6 (1) compels every employer to whom the regulation applies to cause an assessment of the exposure, or likelihood thereof, in the workplace, to be made. Section 9 (1) provides that where a dispute as to an assessment arises, between an employer and either the workers themselves or the joint health and safety committee, an inspector may be notified, whereupon the inspector shall investigate and give a decision in writing. However, should the circumstances require further action on the part of the inspector in order to ensure compliance with the requirements of the regulation, the inspector retains the power to issue an order for a contravention of any section of the Regulation (see section 9 (2)). Consequently, if the Regulation applies to an employer and that employer improperly refuses to conduct an assessment as required by the Regulation, an inspector can issue an enforceable order with respect to the failure to conduct such an assessment. This order would be subject to the usual appeal procedures specified in the Act."

For purposes of clarification, legal counsel has advised that the inspector would issue the order under the powers invested in him under section 29 of The Occupational Health and Safety Act.

7. The development of a mercury regulation for the construction industry

I would like to assure Council that the regulation for the construction industry with respect to mercury will be prepared as soon as possible.

While joint discussions with both construction labour groups and industry representatives will be necessary, this process will be completed as expeditiously as possible.

8. The authority of a Ministry inspector to determine whether respiratory equipment may be provided under section 5 (1) of the mercury regulation

Council questioned "the authority of a Ministry inspector to determine whether respiratory equipment may be provided under Section 5 (1) of the mercury regulation", and whether "an inspector could issue an order to the effect that it is

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not proper to provide respiratory equipment in a particular situation". I have been advised that the answer to both these questions is 'yes' and that an inspector's decision would be in the form of an order.

9. The wording of section 16 (1)

The final point raised by the Council relates to the mandatory removal of workers. Section 16 (1) contains the clause "who shall act thereon" in connection with the duty placed upon an employer to follow the advice of the physician appointed under the mercury control program. The Ministry believes that this wording clearly states that an employer is obligated to remove workers from exposure to mercury when a physician advises that, because of a condition arising from the inhalation, absorption or ingestion of mercury, a worker is unfit for work. Similarly, the employer would take other protective action if the employer is advised that a worker is fit with limitations due to a condition resulting from exposure to mercury.

The Ministry appreciates the Council's concern, but believes the present wording is necessary to cover the wide variety of advice which a physician may provide the employer about a worker's health. The Ministry does not anticipate difficulty with the wording of this section.

10. Amendment to section 3

With respect to sections 3(2) and 3(3), confusion has arisen as to the legal responsibility placed upon the employer in the work place. As these subsections are worded, responsibility for the protection of any worker, whether of the employer or of a contractor, is placed upon the employer in the work place and a contractor has no obligations to his workers under the Regulation. After considering representations that have been made, it has been deemed advisable to redraft subsection (2) to relieve the employer from responsibility towards workers of contractors who are engaged in a construction project in the work place of the employer. At the same time, it was deemed proper to maintain legal responsibility for the protection of all other workers in the work place upon the employer. To accomplish this, subsection 3(2) has been reworded as follows:

> " (2) Subject to subsection (3) an employer to whom this Regulation applies shall take every precaution reasonable in the circumstances to ensure that every worker who is not an employee

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> of the employer but is at, upon, in or near the work place of the employer and is exposed to mercury and whose health is likely to be affected thereby is protected and a worker shall comply with the requirements of the employer. "

The lead regulation will be amended accordingly.

Yours very truly,

Robert G. Elgie, M.D.
Minister

Ontario

Office of the Minister

Ministry
of
Labour

400 University Avenue
Toronto, Ontario
M7A 1T7
(416) 965-4101

March 4, 1982

Dr. J.F. Mustard, Chairman
The Advisory Council on Occupational
Health and Occupational Safety
15th Floor
400 University Avenue
Toronto, Ontario
M7A 1T7

Dear Dr. Mustard:

I am pleased to be able to advise that on the 24th day of February, 1982, His Honour the Lieutenant Governor in Council made a regulation with respect to mercury under the Occupational Health and Safety Act, 1978.

The regulation will be filed with the Registrar of Regulations on the 9th day of March, 1982, and will therefore be enforceable as of that date. Copies of an office consolidation of the regulation and codes will be available to the public on the 9th day of March, 1982.

Attached for your information are three notices that have been prepared to cover the transmission of complimentary copies of the mercury regulation to:

a) interested and affected parties;
b) those parties that participated in the deliberations with respect to the mercury regulation, and
c) organizations which, according to our files, now use mercury or have used mercury in the past.

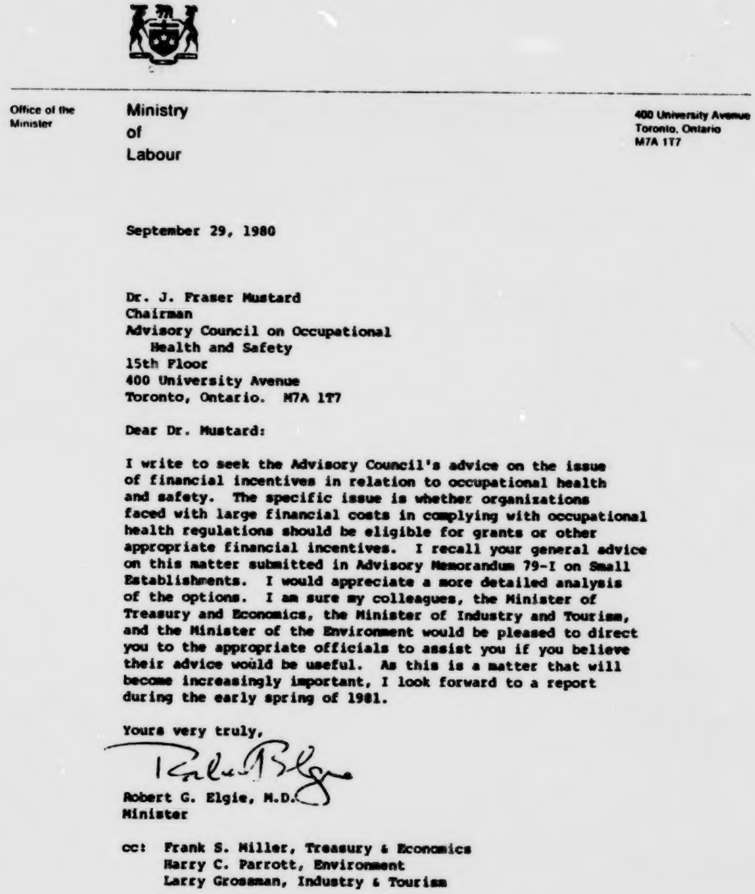
I would like you to thank the members of Council on my behalf for their valuable contribution to the development of the regulation.

Yours truly,

R. H. Ramsay

R.H. Ramsay,
Minister

Advisory Memorandum 81-IV



Office of the
Minister

Ministry
of
Labour

400 University Avenue
Toronto, Ontario
M7A 1T7

September 29, 1980

Dr. J. Fraser Mustard
Chairman
Advisory Council on Occupational
Health and Safety
15th Floor
400 University Avenue
Toronto, Ontario. M7A 1T7

Dear Dr. Mustard:

I write to seek the Advisory Council's advice on the issue of financial incentives in relation to occupational health and safety. The specific issue is whether organizations faced with large financial costs in complying with occupational health regulations should be eligible for grants or other appropriate financial incentives. I recall your general advice on this matter submitted in Advisory Memorandum 79-I on Small Establishments. I would appreciate a more detailed analysis of the options. I am sure my colleagues, the Minister of Treasury and Economics, the Minister of Industry and Tourism, and the Minister of the Environment would be pleased to direct you to the appropriate officials to assist you if you believe their advice would be useful. As this is a matter that will become increasingly important, I look forward to a report during the early spring of 1981.

Yours very truly,

Robert G. Elgie, M.D.
Minister

cc: Frank S. Miller, Treasury & Economics
Harry C. Parrott, Environment
Larry Grossman, Industry & Tourism

Ontario

Advisory Council on
Occupational Health &
Occupational Safety

Office
of the
Chairman

400 University Avenue
Toronto, Ontario
M7A 1T7

416/965-2448

March 30, 1982.

The Honourable Russell H. Ramsay,
Minister of Labour,
14th Floor,
400 University Avenue,
Toronto, Ontario.
M7A 1T7

Dear Mister Minister:

On behalf of the Advisory Council, I am pleased to submit the attached Advisory Memorandum 81-IV on Financial Incentives in the Occupational Health Field.

The former Minister of Labour, Dr. Elgie, had written seeking the advice of Council on the issue of financial incentives in relation to occupational health and safety and identified costs of compliance with occupational health regulations as the specific issue of concern.

As one designated substance regulation has recently come into force and the second has been filed with the Registrar of Regulations and is partially in force, Council hopes that you will find the enclosed advice to be helpful in the implementation of the regulations.

Yours truly,

J. F. Mustard, M.D.,
Chairman.

Attachment

cc: Mr. T. E. Armstrong
Dr. A. E. Robinson

Advisory Memorandum 81-IV
to the Minister of Labour
March 30, 1982

Concerning Financial Incentives in the Occupational Health Field

RECOMMENDATIONS

ACOHOS RECOMMENDATION 81-11

that the Ministry of Labour Occupational Health Laboratory introduce fees for service at competitive market rates for providing direct biologic and other monitoring services, and focus its attention on underserviced areas of the province.

ACOHOS RECOMMENDATION 81-12

that the Ministry of Labour encourage accident prevention associations and labour organizations to develop industry-specific and trade-specific materials addressing programs relative to designated substance regulations and which are suitable for the needs of employers and workers in small as well as large workplaces, and that the Ministry of Labour and the Occupational Health and Safety Resource Centres assist in this work.

ACOHOS RECOMMENDATION 81-13

that the Minister of Labour establish a subsidy program with a ceiling of $15,000 whereby the lesser of the ceiling or 15 per cent of an employer's capital expenditures made to comply with designated substance regulations would be refunded for each substance for which there is a control program (or for a single substance in the case of new plants). Eligibility of the project for a subsidy should be contingent upon review by the joint health and safety committee, if any, of the applicant and review of plans by an engineer of the ministry where normally required.

ACOHOS RECOMMENDATION 81-14

that the Minister of Labour establish guidelines for a loan program for occupational health purposes to be administered through the Development Corporations of Ontario.

INTRODUCTION

The Minister of Labour sought the advice of the advisory council on the question of whether organizations faced with large financial costs in complying with occupational health regulations, should be eligible for grants or other appropriate financial incentives. In examining this matter, council considered the need for financial incentives and their potential role in providing assistance and in serving as an inducement for expeditious compliance with the designated substance regulations currently being promulgated. Further, council reviewed the merits of various financial incentive mechanisms and the criteria to be considered in the implementation of any of these programs.

Although the *Occupational Health and Safety Act* (hereinafter referred to as the Act) does not confine possible regulation in the occupational health and safety field to designated substances, those other regulations currently in force are basically safety regulations which largely represent a consolidation of previously existing regulations. With respect to designated substance regulations, which provide the focus for this review, only the lead regulation and more recently the mercury regulation are in force at this time.* Although these regulations are to be followed by others (asbestos, noise, isocyanates, silica, vinyl chloride, and coke oven emissions are currently proposed for regulation), the number and the time frame of future designated substance regulations is undetermined.

The lead and mercury regulations and the other regulations currently proposed apply to employers and workers at workplaces where the designated substance is present and where the worker is likely to be exposed with certain exemptions as specified in this Act (e.g. farm operations) and in the regulations. Constructors, for example, are exempt from the lead and mercury regulations and the ministry has stated its intention to develop separate designated substance regulations for the construction industry. Proposals set forth in this advisory memorandum, where specific to designated substance regulations, are based on those regulations currently set forward.

GENERAL ISSUES

1) The Treatment of Costs

Council believes that absorption of the costs associated with the occupational health and safety designated substance regulations should be treated as part of the cost of doing business in the long term. However, it is recognized that there may be circumstances when integration of substantial occupational health costs in the short run may produce dislocations and indeed affect the viability of some operations or programs or be incompatible with orderly implementation of the regulations. Council is primarily concerned with short run dislocations and believes this should be the focus of any financial incentive mechanism introduced. In line with this emphasis on addressing the absorption of short run costs to reduce dislocations, this advisory memorandum will concentrate on the impact of hard costs.

In conducting its analysis, council found it useful to categorize the direct compliance costs involved under the headings of 'hard' and 'soft' costs. For the purpose of this advisory memorandum, the term 'soft' costs is used to describe most costs associated with workplace assessments, monitoring, medical surveillance, record keeping, work practices, maintenance of health and safety committees, and training. 'Hard' costs is used to refer to capital costs (including design and structural modifications) involved in engineering controls, provision of hygiene facilities, monitoring equipment, and personal protective equipment. As such, 'hard' costs would entail predominantly, but not exclusively, one time expenditures; 'soft' costs would largely entail ongoing expenditures.

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* The *Regulation respecting lead* came into force August 14, 1981, except sections 4, 5, 7, 8, and 10 to 17, which came into force ninety days after that date on November 12, 1981. The *Regulation respecting mercury* came into force March 9, 1982, except sections 4, 5, 7, 8, and 10 to 17, which are to come into force ninety days after that date on June 7, 1982.

2) The Deficiency of Data

Throughout its work, the Task Force on Financial Incentives encountered uncertainties which made it difficult to gain a clear picture of the magnitude and extent of potential compliance problems, and also left the task force without the tools to measure effectively the potential cost of financial incentive alternatives. Prime among the difficulties was the lack of a comprehensive economic impact assessment or even hard data on the number and size of workplaces to be affected by the various regulations.

Examination of the ministry's *Interim Report on the Designation of Lead in Ontario* (August 1980) provided information on the use of lead and workplace exposure in Ontario including, for example:

- uses of lead in modern industry
- uses of selected commercially important lead compounds
- potential occupational exposures to lead
- types of work with high potential and with some potential for lead exposure.

The interim report also included Ontario Workmen's Compensation Board (WCB) data on claims for lead toxicity or increased lead absorption, and indicated that in 1974 the WCB estimated that about 3,000 workers were exposed to lead and about 25 per cent of these workers were exposed to high concentrations of lead. The report further indicated, however, that the number of workers may be much larger than 3,000 and may involve several hundred workplaces. It went on to state that between 1965 and 1978 the WCB awarded a total of 292 claims related to lead exposure at an average of about 20 to 25 claims per year and that, in the latter half of this period, the average increased slightly to about 28 claims per annum (in the first half, the average was 14). The report pointed out that this does not mean that the incidence of lead intoxication is rising, but rather reflects the greater awareness, on the part of workers and industry, of the hazards of lead which had led to early detection of adverse health effects due to lead exposure.

Data on use and exposure received fairly similar treatment in the interim reports on the designation of other substances, but, on the whole, the approach left the task force without a high degree of confidence on the extent of worker exposure. In the case of lead, the ministry has expressed the view that lead has been the subject of control in Ontario for some period of time, and that the proposed regulation should not significantly change the current control practices of lead users. Nonetheless, the task force found the lack of more comprehensive data disturbing, particularly with respect to small workplaces.

A review of correspondence and briefs submitted to the ministry in response to the public notice of the ministry's intention to regulate certain designated substances and in response to the proposed regulations themselves, revealed numerous suggestions of the need for provision by the ministry of economic impact or cost-benefit data. For some regulations, it was clear that a number of sectors anticipated inordinate difficulties in complying with the regulations by means of engineering controls. However, in general, the submissions did not themselves yield extensive economic impact information.

To give some substance to an examination of compliance costs, the task force reviewed the experience of several firms in implementing control programs to cope with high levels of lead and noise. The task force also consulted an Occupational Health and Safety Resource Centre which had had experience with a number of designated substances and which had done substantial work in the area of noise. In these approaches, the task force looked at the various types of costs which could be expected to be associated with compliance with designated substance regulations. In addition to attempting to come to grips with the magnitude of the cost elements, the task force was concerned with determining how the impact of the regulations would vary between different workplaces.

Some anecdotal information relating to the impact of the lead regulation on small firms was provided by preliminary results of a survey being undertaken by a 'Small Firms Committee' which was set up early in 1980 on the initiative of the Industrial Accident Prevention Association and the Small Business Development Branch of the then Ministry of Industry and Tourism to study the impact on the small firm of Ontario's health and safety legislation, and to formulate ways and means of providing small firms with financial, technical and educational assistance in the development of occupational health and safety programs.

Most prospective firms approached for the purpose of the survey were found to be unaware of the regulation, despite the fact that it had been in force for a number of months, and it was found necessary to develop a different approach, describing the requirements in the regulation in a way which would more readily enable meaningful interpretation by small employers.

Preliminary survey work with four co-operating firms working with lead revealed the following:

- None of the four firms had been aware of the regulation of lead and they were only vague in their knowledge of the Act.
- One firm involved in steel fabricating and using lead oxide paint believed it would be necessary to spend 'a lot' of money for 14 employees and that it would also have to comply with regulations for silica and isocyanates.
- In a firm repackaging lead paste for the building trade, there was possible exposure to lead through skin contact. Although the possibility of exposure was minimal, the employer determined it would be preferable to eliminate that phase of involvement with the product rather than have to deal with the regulation.
- The third firm worked with molten lead and was one in which the ministry had carried out testing for airborne lead. Although that testing determined there was no exposure problem while the system was operating correctly, failure of the extraction system would result in high exposure. It was unclear whether other engineering controls would be necessary and the extent to which the regulation would apply.

- A fourth firm, operating in the chemical sector, used large quantities of lead as well as polyvinyl chloride. It did not appear that the ministry had first-hand knowledge of this firm. It was expected the financial impact of the regulation would be great.

While no cost estimates were possible from these preliminary findings, the task force felt that these impressions were not inconsistent with its own expectations and did not feel that final findings would substantially alter its recommendations for financial incentives.

3) The Nature of the Impact

The burden of compliance can be said to be characterized by a general lack of uniformity, both in absolute and in relative terms. Among the factors which one would expect would cause disparities would be:

- nature of the work or process
- type and number of designated substances in the workplace
- nature of worker exposure
- timing of the regulations (e.g. extent to which the workplace is already in compliance)
- size of the workplace (e.g. number of employees).

Some further factors which would account for differences in impact include the extent to which expenditures for 'soft' costs and 'hard' costs are substitutable, the extent to which compliance expenditures reduce the employer's tax burden, the extent to which costs can be passed on in the form of higher consumer prices or lower labour costs, and the labour intensity of the production technology.

It has been noted that timing can have a definite bearing on the immediate impact of regulation. Actual compliance costs for employers who have already moved to implement comprehensive control programs may be lower than for those who have not taken such steps, but the expenditures have been made and the impact absorbed nonetheless.

However, even for employers who have previously implemented appropriate control programs, the regulations can be expected to change some costs associated with these programs. For example, the prototype lead regulation specifies that 'a worker shall, at the expense of the employer, undergo the medical examinations and clinical tests required under the lead control program.' It is council's understanding that, as well as other costs associated with clinical tests, employers will ultimately be expected to pay for clinical tests which have in the past been performed without charge by the ministry laboratory.

BIOLOGICAL MONITORING SERVICES

In Advisory Memorandum 79-I, ACOHOS Recommendation 79-10, council recommended that, as a long-term goal, the Ministry of Labour plan to withdraw from providing direct biologic or other monitoring services.

The ministry in its response stated that:

> 'The ministry supports and will encourage the establishment of private sector occupational health services. The need for expanding a private sector service is well recognized, and it is hoped that professionals capable of providing the required services will quickly establish the various enterprises and facilities that are needed. Unfortunately, the potential demand for occupational health and safety services does not appear to have been fully recognized by many professionals capable of providing such services. Some stimulation of private economic initiative may be necessary therefore, particularly in remote areas. The ministry, along with the Ministry of Industry and Tourism, is exploring the council's suggestions on subsidies and incentives. Other methods of encouraging the establishment of private sector services will also be explored.
>
> 'The ministry will continue to maintain the health screening and laboratory services that are currently provided, at least until an adequate private sector network is established and operational. In order to conserve scarce financial resources and maintain services essential to the ministry's legislative mandate, consideration may have to be given to the charging of fees for services that are currently available free to service users.'

Council is pleased to note that the ministry is considering the application of user charges for laboratory services. It notes, however, that there are other compelling reasons for this policy besides the need to conserve scarce public resources. One reason the private sector occupational health and safety services may not have developed as fully as might have been hoped or expected is that it is naturally difficult to compete with a ministry which provides these services without charge. Council feels that the ministry should be one among many providers of services in this field and should focus attention on underserviced areas. In order to encourage such a development, the ministry should be charging competitive market fees. In remote areas, Occupational Health and Safety Resource Centres can perhaps provide supplementary back-up services and expertise to enable private firms or groups to provide occupational health services in areas which might otherwise be uneconomical to pursue.

It is important that private laboratories achieve and maintain a high standard. It is particularly important that private laboratories warrant a high level of confidence among workers. To ensure that private laboratories achieve and maintain a high standard, the public laboratory should also be available in order to exercise an audit function.

ACOHOS RECOMMENDATION 81-11

> that the Ministry of Labour Occupational Health Laboratory introduce fees for service at competitive market rates for providing direct biologic and other monitoring services and focus its attention on underserviced areas of the province.

SMALL ESTABLISHMENTS

In Advisory Memorandum 79-1 on Occupational Health and Safety Programs for Small Establishments, council identified a number of factors militating against small establishments setting up formal health programs. Some of the obstacles envisaged were lack of sufficient time or personnel to specialize in a particular issue, such as occupational health and safety, and greater difficulty in obtaining finances. Council recommended at that time (ACOHOS Recommendation 79-11A) that the government create a limited subsidy program to be available to those small businesses in special circumstances, arising from their geographic remoteness or economic condition, which make it particularly difficult for them to provide occupational health and safety services for their employees.

The Task Force on Financial Incentives concurred with the earlier findings of difficulties facing small establishments, and further recognized that, other things beings equal, the per employee cost of carrying out workplace assessments, medical surveillance, monitoring, record keeping, and other 'soft' costs associated with regulation may be relatively greater for small workplaces lacking the advantages of economies of scale. In the case of some small workplaces which are part of multi-establishment organizations, some possibilities do exist for benefitting from economies of scale as well as for overcoming other obstacles. In general, however, council feels that lack of technical information, expertise, and knowledge of reliable sources of commodities and specialized equipment and services required to comply with the regulations may be an obstacle facing small firms, and may leave them without the ability to be sophisticated consumers of consulting services offered by engineering firms and occupational health program consultants.

While agreeing with the general philosophy of Recommendation 79-11A, council feels that the new designated substance regulations, and especially the costs involved in engineering controls stemming from those regulations, call for a reorientation of the proposed subsidy program. Owing to the nature of the problems specific to small firms, council feels that there may be other effective mechanisms for addressing those problems without the administrative structure implied in a program to subsidize the soft costs involved in setting up and maintaining occupational health programs.

A number of existing organizations are presently carrying on activities which may be able to further assist small employers in overcoming information-related problems. Accident prevention associations have been actively involved in developing trade-specific and industry-specific hazard identification materials. Further, a number of the accident prevention associations have taken on and/or have been involved in new initiatives which have significance for the designated substance regulations. For example, the Industrial Accident Prevention Association has developed materials to assist joint health and safety committees in becoming established and in carrying out their functions. A number of labour organizations also play an active counselling and training role in these areas. The Ontario Federation of Labour, for example, is developing training modules with respect to lead to assist member workers in exercising the rights and fulfilling the responsibilities of workers in the implementation of the regulation.

Council feels that the accident prevention associations and labour organizations should further supplement the ministry's role as a resource and be further encouraged to develop trade-specific and industry-specific materials addressing programs relative to regulated designated substances. Such materials should be designed to include the needs of employers and workers in small as well as large workplaces. The existing Occupational Health and Safety Resource Centres and the Ministry of Labour could also assist such agencies in preparation of this material and in identification of types of workplaces for which this would be appropriate. Consultation between the various groups should be maintained to assure that unnecessary duplication is avoided, that materials be developed jointly or in co-operation where advisable, and that dissemination of information to employers and workers be optimized. Particular attention should be paid to exploring means of ensuring that small firms to whom designated substance regulations apply are aware of the availability of such materials and have ready access to them.

Council has, on other occasions, reflected on the valuable role the accident prevention associations can play in providing a forum for the exchange of information and expertise between large companies and smaller ones. The designated substance regulations are a case in point where the associations and other groups should strive to fulfil this role and, in so doing, the needs of employers and workers in non-unionized small workplaces should not be overlooked.

ACOHOS RECOMMENDATION 81-12

> that the Ministry of Labour encourage accident prevention associations and labour organizations to develop industry-specific and trade-specific materials addressing programs relative to designated substance regulations and which are suitable for the needs of employers and workers in small as well as large workplaces, and that the Ministry of Labour and the Occupational Health and Safety Resource Centres assist in this work.

FINANCIAL INCENTIVE MECHANISMS

Council has suggested that the new designated substance regulations, especially in light of the emphasis in those regulations on the use of engineering controls, call for a reorientation in the subsidy program proposed in Recommendation 79-11A. Costs associated with engineering controls, provision of hygiene facilities, and monitoring equipment, 'hard' costs in our terminology, could be potentially very difficult to absorb in the short run. Moreover, the benefits of control programs are often subtle and diffused and may not be promptly reflected in cost savings. Limitations to the effectiveness of fines/penalties and workers' compensation assessments as economic incentives are recognized, as are the enforcement difficulties associated with regulations applying to large numbers of workplaces. In order to reduce the disruption, ease the burden and assist in providing orderly implementation of the regulations, council believes that there is a place for a financial incentive program.

Among the factors which council considered in assessing financial incentive mechanisms were the effectiveness and efficiency of the mechanisms and the distribution of the benefits, both from the point of view of the potential recipient as well as of the agency providing and administering the incentive program. It was further essential to bear in mind the potential dislocations which may result *vis à vis* firms' competitive positions. Due regard was given to the fact that some financial 'incentive' options may not in themselves act as incentives, but merely as forms of assistance once expenditure decisions have already been made. However, in the case of designated substance regulations, a mechanism was sought which would provide incentive for compliance when working in conjunction with the incentives in the Act and in the designated substance regulations themselves and with enforcement of these legislative requirements.

In its Advisory Memorandum 79-I, council had considered tax credits as a subsidy mechanism and determined that tax credits would not assist a sufficient number of small establishments. Further, those small establishments which would qualify because they paid sufficient tax may well be those least in need of assistance. For these reasons, council did not recommend tax credits as part of an incentive scheme.

The Task Force on Financial Incentives explored the merits and demerits of tax credits and alternative forms of assistance and incentives including variations of grants, loans, sales tax exemptions or refunds, accelerated capital cost allowances and tariff reductions, and weighed their suitability in terms of the particular demands and effects of the regulations. These options were considered with regard to suppliers, as well as consumers of goods and services. The difficulties and disadvantages inherent in mechanisms hinging on federal co-operation were also important determining factors in evaluating possible mechanisms.

A subsidy program devised for the purposes described should ideally be structured so that it can be administered with a minimum of difficulty and so that workplaces should not be made ineligible by reason of their structure (e.g. incorporated versus unincorporated). The distribution and nature of the economic impact of compliance with designated substance regulations is likely to vary considerably, and council sees the most appropriate and sensitive mechanism in this instance being in the form of a refund of a portion of 'hard' costs undertaken in respect of designated substances control programs.

Considerable flexibility is possible in the design of such a subsidy, and council considered, at some length, the desirability of assisting small versus large employers and the implications of creating a differential subsidy or restricting the subsidy to small employers. Absence of economies of scale, as well as lack of information and specialized occupational health personnel and expertise were noted as factors which may put small employers at a disadvantage relative to larger employers. Although the regulations apply to, and have an impact on, employers irrespective of their size and are concerned with the health and safety of workers in workplaces of all sizes, workers in small workplaces may be at higher risk. Many large employers have already moved to institute health and safety programs in a comprehensive way which has not been manifested in small workplaces; enforcement of regulations will, in all likelihood, be more difficult in small workplaces; information and understanding problems are generally more complex with respect to hazardous substances than they are for safety problems, and this difficulty is magnified for the small workplace.

The number of large workplaces in Ontario is small relative to the number of small workplaces, although large workplaces employ a much larger proportion of the work force. For example, in the manufacturing sector in 1979 there were 12,301 establishments with less than 100 employees compared to 1,803 establishments (approximately 13 per cent of the total number) with 100 or more employees, while those establishments with 100 employees or more accounted for approximately 75 per cent of total manufacturing employment.

A matter of further importance in the consideration of differential subsidies is that of definition. The Task Force on Small Business had considered definitional problems in some depth and was unable to arrive at what was felt to be a satisfactory definition of small establishments. Because of the nature of the impact of designated substance regulations, selection of virtually any size or financial criteria as a basis for creating differential subsidies would, of necessity, be arbitrary. Many workplaces have provisions for work arrangements other than regular full time, and the treatment of these arrangements in determining the 'number' of workers in a workplace would again be arbitrary. In the selection of any number or definition to establish a differential subsidy, there is the further and undesirable risk that some employers would make marginal changes in the size or work arrangements of their work force in order to qualify for a larger subsidy.

A subsidy program intended to lessen dislocations caused by regulation should minimize the extent to which it introduces further and inequitable dislocations. On the basis of the considerations outlined above, council believes that large workplaces should not be excluded from the subsidy program, but that a program which targets small workplaces is warranted. Rather than introducing arbitrarily selected criteria, such as size, as a basis for differentiation, a ceiling on the total value of expenditures eligible for a subsidy is thought to be a more appropriate method of creating the desired differential effect.

The financial incentive proposed would be in the form of a refund or rebate of 15 per cent of the 'hard' costs undertaken in any workplace, in respect of designated substance control programs. To be effective, it would be preferable that the refund be provided within 60 days of submission of a claim, the expenditure already having been undertaken and supported by invoices. The refund program should incorporate a ceiling limiting the subsidy to a maximum amount for each designated substance control program undertaken in each separate workplace — the ministry to follow its normal practice in determining what constitutes a separate workplace. It is suggested that a ceiling of $15,000 (i.e. the lesser of $15,000 or 15 per cent of 'hard' costs) may be an appropriate maximum.

As more regulations come into place and better information is developed on the economic impact of the regulations, the appropriate level for this ceiling might be adjusted. In any event, while establishments of any size would be eligible for the rebate, the ceiling feature would tend to result in relatively greater benefits falling on small workplaces. At about 15 per cent (approximately double the retail sales tax), the assistance provided would ease the financial burden of compliance and give more visibility to the regulation program.

The program should not be permanent, but should be terminated five years after the particular regulations have come into force and, for those regulations already in force, should be made retroactive to the date at which the regulations came into force.

One difficulty which might be anticipated with a formula bringing a subsidy into effect at the time of regulation is that it could give rise to cases of postponement of improvements which would otherwise have been made prior to regulation. It is felt, however, that large and financially sound organizations would be most likely to be those which would ordinarily be in compliance in advance of regulation and that the ceiling provision would minimize the extent to which expenditures would be delayed.

Council believes this subsidy should also apply in the case of new plants since it would be inadvisable to create biases in favour of old production facilities. However, it is required that plans for new plants be filed in advance with the ministry for review by an engineer of the ministry for compliance with the Act and the regulations, and it is expected that the mandated occupational health and safety features would be an integral part of the plans for any new workplace. For these reasons, new plants would be eligible to submit an application for only one refund regardless of the number of designated substance regulations which apply.

Certain measures could be taken which would minimize the administration involved in the processing of claims and the degree of inspection required, provide a check on the system and ensure that the expenditures are a necessary and legitimate part of a control program. One of the pre-conditions for eligibility for a refund should be that evidence be provided that the expenditures have been undertaken in consultation with, and after review by, the joint health and safety committee (i.e. committee as defined under the Act), and that plans have been reviewed by an engineer of the ministry where normally required [in accordance with subsection (3) of section 18 of the Act]. Where the Act does not provide for either a joint health and safety committee* or for review by an engineer of the ministry, the option of one of these conditions or of review by the ministry should nonetheless be made necessary for eligibility for a subsidy. Such evidence should include a statement on the nature of the current lack of conformity with the regulation and the effect that the expenditures would have in bringing the workplace into conformity with the requirements of the regulation. The subsidy program should be administered by the Ministry of Labour and should include provision for audit. A supplementary benefit foreseen in putting such a program in place is that an information base, imperfect as it may be, would start to be generated on the real impact of compliance with the regulations.

ACOHOS RECOMMENDATION 81-13

> that the Minister of Labour establish a subsidy program with a ceiling of $15,000 whereby the lesser of the ceiling or 15 per cent of an employer's capital expenditures made to comply with designated substance regulations would be refunded for each substance for which there is a control program (or for a single substance in the case of new plants). Eligibility of the project for a subsidy should be contingent upon review by the joint

---

* In certain circumstances the Act does not provide for joint health and safety committees. See section 8(1) of the Act.

health and safety committee, if any, of the applicant and review of plans by an engineer of the ministry where normally required.

The cost of such a subsidy program would depend on the substance to which it applied, the dollar ceiling set for that substance, the rate of uptake and the extent to which applicants were eligible for the full subsidy. With respect to organizations using lead, the ministry has identified some 270 different manufacturers. If even half of those currently identified as using lead were to qualify for the maximum subsidy, the cost of the program in addressing the problem of instituting engineering controls for lead (assuming an equal distribution of disbursements over a five-year period) would be approximately $400,000 per year.

Council has indicated a preference for using a ceiling as a mechanism for targetting small firms. The arbitrary nature of size criteria and definitions was among the reasons for this preference. However, it is recognized that these definitions are at times made and that it may be felt important to have a program which more visibly targets small workplaces. Therefore, council suggests an alternative proposal for addressing this, which would roughly balance the cost involved in Recommendation 81-13, but would differ from that recommendation in the following respects:

- For workplaces with 100 or more employees, applicants would be eligible for a 10 per cent refund on capital expenditures.
- For workplaces with less than 100 employees, applicants would be eligible for a 15 per cent refund on capital expenditures.
- The ceiling on eligible capital expenditures, where suggested as $100,000 in the case of the lead regulation, would be increased to $125,000.
- 'Large' employers would be eligible for a maximum subsidy of $12,500 per designated substance control program.
- 'Small' employers would be eligible for a maximum subsidy of $18,750 per designated substance control program.

Council further feels that in view of the fact that some firms will undoubtedly experience great difficulty in obtaining financing to comply with the designated substance regulations, regardless of what subsidy programs are available, another avenue should be opened. The Development Corporations of Ontario provide loans for pollution control equipment and, although few loans have been made for that purpose, council feels that a similar loan provision should be made for equipment or modifications that may be required for occupational health purposes.

ACOHOS RECOMMENDATION 81-14

that the Minister of Labour establish guidelines for a loan program for occupational health purposes to be administered through the Development Corporations of Ontario.

Acknowledgements

The membership of the task force included four members of the Advisory Council on Occupational Health and Occupational Safety and two outside experts. The council members were Dr. A. D. Wolfson (chairman), Mr. P. A. Fisher, Dr. R. D. Fraser and Mr. C. G. Pilkey. The non-council members chosen to serve on the task force were Mrs. V. M. Kempston-Darkes and Mr. I. L. Rosen. To supplement its own knowledge, the task force consulted a number of individuals and organizations. It wishes to express its appreciation to the following:

Mr. H. D. Forbes - Small Business Development Branch, Ministry of Industry and Trade Development
Mr. D. F. Hutton, Mr. G. Hearns and Mr. B. Scott — Canada Metal Company Limited
Mr. R. C. Walter and Mr. R. Andrew — General Motors of Canada Limited
Mr. A. D. Heath, Ms. Sharon Jorgenson and Ms. Mary Spencer — Standards and Programs Branch, Ministry of Labour
Mr. A. L. Gladstone — Occupational Health and Safety Division, Ministry of Labour
Mr. J. A. Donnan — Program Planning and Evaluation Branch, Ministry of the Environment
Dr. R. E. M. Lees — Occupational Health and Safety Resource Centre, Queen's University
Ms. N. Bardecki — Fiscal Planning Policy Branch, Ministry of Treasury and Economics

Small Firms Committee:
Mr. G. E. Hale (committee chaiman) — Canadian Organization of Small Business.
Mr. E. L. Trelford — Standards and Programs Branch, Ministry of Labour.

The task force would also like to extend its appreciation to the chairman of the Small Firms Committee for the invitation offered to the resource person on council staff to attend meetings of the committee.

Ontario

Office of the
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April 16, 1982

Dr. J. F. Mustard,
Chairman,
Advisory Council on Occupational
Health and Occupational Safety,
15th Floor,
400 University Avenue,
Toronto, Ontario
M7A 1T7

Dear Dr. Mustard:

Thank you for your letter of March 30, 1982, submitting to me Advisory Memorandum 81-IV on Financial Incentives in the Occupational Health Field.

I am most interested in the recommendations on the financial incentives that should be used to help business implement effective occupational health and safety programs and to comply with the regulations.

I will send you my formal response as soon as I have consulted with my Cabinet colleagues on the feasibility of implementing your recommendations.

Yours sincerely,

R. H. Ramsay,
Minister.

Follow-up Correspondence to Previous Advisory Memorandum 80-IV

Ontario

Advisory Council on
Occupational Health &
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of the
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416/965-2448

November 17, 1981.

The Hon. Robert G. Elgie, M.D.,
Minister of Labour,
400 University Avenue, 14th Floor,
TORONTO, Ontario.
M7A 1T7

Dear Dr. Elgie:

Re: Advisory Memorandum 80-IV on the Use of Information to Prevent Occupational Accidents and Illnesses

On March 25, 1981, council submitted for your consideration Advisory Memorandum 80-IV which dealt with policies and principles for the use of information in the prevention of occupational accidents and illnesses. This memorandum contained a series of recommendations which council anticipated would improve existing practices for the collection, analysis, distribution and use of occupational health and safety information. On April 15, 1981, council received from your office a response to the recommendations contained in Advisory Memorandum 80-IV. In its review of this response, council was left with the impression that the intent of some of its recommendations may not have been clear. In order to clarify its position, council would like to add the following comments in respect to the recommendations noted below:

a) The Minister's Response to Recommendation 80-24.

In this recommendation, council advised the Ministry of Labour, in consultation with the Workmen's Compensation Board, to take the steps necessary to coordinate a system of uniform data collection within the province. The recommendation went on to state that the restructured system should reflect the fact that the data requirements for compensation and rehabilitation are quite different from the data requirements for accident prevention and that the two categories require independent attention. Furthermore, the users of occupational safety data should be given the opportunity to make submissions to the ministry in regard to their specific data needs.

In the response to this recommendation, you stated that you would request that the Workmen's Compensation Board consult with the Council of Safety Associations to determine how the quality of accident causation data recorded on form 7s could be improved, and whether separate accident causation forms should be developed by the safety associations. It was your general conclusion, however, that "the existing system meets, in large part, the requirements of users and provides a good basis for the development of more comprehensive and detailed systems in the long term."

When members of the Task Force on Information canvassed this subject, it was concluded that the current system of data collection and analysis, which is based on the WCB's form 7, is unable to answer some crucial questions relative to accident prevention. For example, it is difficult to obtain accurate and detailed information on specific accident types across different industries. It is also difficult to calculate injury rates, severity rates and fatality rates for different occupations, and to cross-reference these statistics to variables such as age of worker, number of years of experience and type of equipment or process involved. Information of this sort must be available in order to systematically address workplace hazards and to develop a system for the in-depth causal investigation of specific accident types.

Council agrees that the form 7 utilized by the WCB could be likened to the first tier of a model system for the collection and interpretation of accident information. Council's point is, however, that the form 7, as presently conceived, is unable to elicit a range of data sufficient for accident prevention purposes. This view, it should be noted, is shared by the Joint Federal-Provincial Inquiry Commission into Safety in Mines and Mining Operations, which, at page 157 of its report, states:

> "The form submitted by the employer to the Workmen's Compensation Board (form 7) in conjunction with each accidental injury or industrial disease, is presently used to obtain the information necessary to identify causes of accidents. However, the primary purpose of this form is to provide information upon which to judge compensation claims. It is not surprising, therefore, that this form is inadequate as a means of identifying the causes of accidents."

In order to obtain a concensus on the type of information that should be coded on form 7s, council encourages you to discuss this subject with the WCB, the safety associations and other users of accident data.

b) The Minister's Response to Recommendation 80-25.

In this recommendation, council advised that, once a coordinated system for data collection had been put into effect, the Ministry of Labour should ensure that a common data base is established to meet the information requirements of the ministry, the Workmen's Compensation Board, the accident prevention associations and other users.

In the response to this recommendation, it was stated that a common data base (the ministry's work injury information system) already exists "that suits the needs of major users". It was also noted that this system is undergoing further development.

When the Task Force on Information conducted meetings with the users of accident data, several parties, notably the safety associations, made it clear that they did not consider the information bases developed by the WCB and the ministry to meet their requirements for accident prevention. Furthermore, council wishes to draw to your attention the fact that interested groups outside the ministry were not consulted when the work injury information system was being developed. It might, therefore, prove useful for the ministry to consult with the users of accident data to ensure that council has summarized their concerns in an accurate fashion.

c) The Minister's Response to Recommendation 80-26.

In this recommendation, council advised the Minister of Labour and the Workmen's Compensation Board to encourage the development of a tiered system of data collection for workplace accidents. It was recommended that an arrangement of this sort should include a simple universal system for the collection of general data and a selective system for the more detailed investigation of those accidents that cause death or serious disabilities.

In response to recommendation 80-26, you stated that elements of the three-tiered system recommended by council are already in existence. Tier 1 is represented by the WCB's form 7; tier 2 is currently within the scope of the ministry's work injury information system; and tier 3 could be likened to the investigations conducted by the three line branches of the ministry.

Council is pleased to see that the ministry recognizes the merits of a three-tiered approach for the collection and interpretation of data on accidents. Council notes that, while a three-tiered structure may currently be in place, there is a difference of opinion on the question of whether the second and third tiers (the work injury information system and the investigations conducted by the line branches) have the sophistication necessary to unearth detailed information on accident causation. Part of the problem lies in the fact that the work injury information system is based on an inadequate first tier, namely the form 7.

Council suggests that, in order to maximize the benefits that could be produced from a three-tiered approach to data collection and interpretation, the ministry set up a working group with the WCB and the users of accident data to determine how the second and third tiers could be refined to better suit the needs of all parties.

d) The Minister's Response to Recommendation 80-27.

In recommendation 80-27, council advised the Minister of Labour to encourage the Workmen's Compensation Board to identify, within broad segments of industry, the types of accidents that are responsible for the greatest degree of human injury and disability. Council also recommended that the minister ask the board to develop protocols, in consultation with companies, labour and the accident prevention associations for the detailed causal investigation of accidents of this type. Such investigations, it was emphasized, should not be used as substitutes for the investigative processes ordinarily conducted by the ministry for purposes of enforcement.

In response to council's recommendation, you pointed out that the IAPA and the CSAO have developed and are working with data collection and analytical systems which may provide detailed causal information on specific classes of accidents. You also undertook to seek the views of the WCB on the development of protocols for the detailed causal investigation of specific accident types.

In its deliberations, council's Task Force on Information concluded that the accident information systems developed by the safety associations are geared primarily towards eliciting higher quality descriptive data on accidents and are not aimed at unearthing faults within the managed system. Consequently, council is concerned that a formal mechanism does not appear to exist for i) the identification of accident types that are responsible for the greatest degree of human injury and disability, and ii) the investigation of these accidents in detail for cause.

e) The Minister's Responses to Recommendations 80-30 and 80-35.

Council would like to obtain clarification in respect to the responses made to recommendations 80-30 and 80-35.

In recommendation 80-30, council advised the Minister of Labour to ensure that all Ministry of Labour and Workmen's Compensation Board files containing information on a worker's occupational disease claims and medical history include a unique personal identifier. In addition, council stated that the minister should require that all records of exposure to carcinogenic and toxic agents kept pursuant to The Occupational Health and Safety Act and regulations contain a unique personal identifier.

In response to this recommendation, you stated that the Government of Ontario recognizes the need for a common identifier to facilitate record linkage in the field of occupational health and safety. You added, however, that the use of personal identifiers must be based on policy guidelines developed by the provincial government. It was suggested, further, that such guidelines would be forthcoming on June 30, 1981.

The government guidelines were, in fact, promulgated on June 30, 1981. In respect to the coding of unique personal identifiers on health records, the operative portion of the guideline states:

> "pending a decision to establish a unique personal identifier for health programs, the social insurance number may be used as an identifier for medical information".

The provincial government's guideline would seem to suggest that, in the short run, the ministry could require that social insurance numbers be coded on all medical and exposure records, maintained pursuant to The Occupational Health and Safety Act. Council notes, however, that in The Code for Medical Surveillance for Lead, the coding of social insurance numbers on medical history and examination records is not required, but merely recommended. Council wonders whether the ministry would now be prepared to reconsider council's recommendation that medical and exposure records be required to contain a unique personal identifier.

In recommendation 80-35, council advised the Minister of Labour to cause a provision to be added to The Occupational

Health and Safety Act which would require that all employers who keep and maintain medical and exposure records pursuant to the act, inform the ministry of this fact.

In response to this recommendation, you stated that, when the designated substances regulations are in place, the ministry will monitor their effectiveness at the workplace.

The intent of recommendation 80-35 was to ensure that a formal mechanism is in place to provide the ministry with information on the existence of exposure and medical records. Council notes that this objective could be achieved without the necessity of amending the Act, if each designated substances regulation contained an appropriate notification provision.

Council's purpose in submitting this letter to you is to ensure that there is maximum understanding of the intent of our recommendations. Should you feel it desirable, council members would be pleased to meet with your officials to elaborate upon any of the points raised in this letter.

Yours truly,

Dr. J. F. Mustard,
Chairman.

cc to: Mr. T. Armstrong
Dr. A. Robinson

Report of the Special Advisory Committee on Carcinogens

- J. F. Mustard, MD, PhD, FRCP (C) (Chairman)
- E. Farber, MD, PhD, FRSC
- A. B. Miller, MB, FRCP (C)
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April 7, 1982

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Report of the Special Advisory Committee on Carcinogens

1. INTRODUCTION

The suggestion that substances in the workplace might cause cancer was first made by Percival Pott in 1775 on the basis of his experience with scrotal cancer in chimney sweeps. The substances which were identified as causing cancer in these early chimney sweeps are still being inhaled by individuals such as coke oven workers, some of whom are dying of lung cancer at a rate 10 times higher than other steel workers.

In the past, the effects of carcinogenic substances have been deduced by observing that cohorts of individuals exposed to a substance show an increased incidence of cancer. It is now well established that chemical substances can cause cancer, and it is possible to predict, with reasonable reliability, by means of appropriate tests, the potential of a substance to be a carcinogen.

The first part of this report sets forth some general facts about cancer and about cancer deaths in Ontario. The second part consists of summaries of four 'case histories'*, which illustrate what is known about carcinogens and environmental and lifestyle factors that can cause cancer. The report then looks at the overall cancer burden in Ontario and gives consideration to strategies and methods for screening new substances.

2. THE BIOLOGY OF CANCER

Simply put, cancers arise when cells lose their 'social inhibitions'. These altered cells fail to recognize the signals that regulate their normal functions, growth and location in the organism. As a result, these cells proliferate to form tumour masses. When they keep within their normal territory and do not invade the surrounding tissues, they form 'benign' tumours. If the abnormal cells spread into neighbouring tissues or to distant regions by way of the circulation, they are termed 'malignant' tumours or cancers.

Cancers are classified according to cell type: the carcinomas arise from the sheets of cells covering the exterior and interior (e.g. mouth) surfaces of the body and lining the various glands i.e. epithelial cells; sarcomas arise in supporting tissues (such as bone cells, blood vessels and muscle). Leukemias and lymphomas involve abnormal proliferation of blood cells or their precursors. More than 90 per cent of human cancers arise in epithelial cells, mainly in the surface ephithelia such as the skin, airways and digestive tract, which are in direct contact with the substances of the outside world.

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*–the complete texts are to be found in Appendices A-D.

The transformation of normal cells to malignant cancer cells is a complex, multi-step process which is still not well understood. It is clear, however, that carcinogenic chemicals, ionizing and UV radiation can increase the rate at which some of the steps take place and thus greatly increase the probability of a tumour appearing in an exposed individual.

Study of the causes of cancer is complicated by the fact that there is a period of 5-40 years between initial exposure to the agent(s) that causes cancer and the clinical appearance of tumours.

The evolution of a normal cell into a tumour cell begins with an event referred to as 'initiation', which is generally believed to involve damage to chromosomal DNA by the carcinogen (or by a reactive derivative formed from the carcinogen by metabolic processes within the body). The consequence of such damage may be gene mutation, chromosomal rearrangements or alterations in cellular control mechanisms which accomplish one of the steps required in the development of malignancy. Compounds such as benzo(a)pyrene, vinyl chloride, β-naphthylamine and agents such as UV light and ionizing radiation are considered to be 'initiators'. With most initiators, large or repeated doses suffice to cause tumours without the need for additional stimuli. Other compounds such as catechol, pyrogallol, pyrene and benzo(e)pyrene, which do not themselves initiate cancers, may increase the potency of initiating carcinogens *if present simultaneously*. Such compounds are called 'co-carcinogens'.

Initiated cells are not yet malignant, and other events are required before malignancy is manifested. While detailed knowledge of these important events is scanty, it is established that chemicals can also influence the rate at which these events take place. One well-studied (but poorly understood) phenomenon is that of 'promotion' in which a compound which does not 'initiate' tumour development can greatly increase the rate of evolution of cells which have previously been 'initiated' with such low doses of carcinogens that few, if any, tumours would have been induced by the initiator alone. Promoters can exert their influence even when applied long after the initiation event. The classical example of a tumour-promoting substance is croton oil—a highly irritating plant material. However, in experimental animals, other substances, including phenol, anthralin and n-dodecane, are promoters for skin tumours and saccharin is probably a promoter for bladder tumours. Various mechanisms have been suggested to account for promotion. These include stimulation of cell division, membrane changes, and induction of enzymes, but again, the specific mechanisms have not been established.

It seems probable that exposure of humans to environmental (including occupational) or 'life style' initiators will cause initiation events in some cells. In the absence of promoters, these cells may remain quiescent, whereas in the presence of promoters, they may have a much higher probability of developing into malignant tumours. Thus, from the point of view of cancer prevention, it may be as important to minimize the exposure of humans to promoters as to minimize exposure to initiators.

While a later section of this report deals in detail with assay systems for carcinogens, it is worth noting that there are now reasonably useful routine assay systems for the detection of initiators, but that assays for the detection of promoters are in a much more primitive state.

Lessons

1. The development of cancer involves many steps; interfering successfully with any of these could prevent the onset of malignant disease.
2. Environmental or lifestyle initiators of cancer need attention, but so do promoters.

3. SUMMARIES OF CASE HISTORIES

Following are summaries of the four 'case histories' referred to in the introduction. The purpose of these case histories is to provide examples of universally recognized carcinogens and to identify the cancers which they are known to produce, with particular reference to how the carcinogens were eventually identified. The examples are chosen for the clarity of the evidence, not because they specifically identify lifestyle or environmental factors.

1. Ionizing Radiation

The early workers with ionizing radiation were unaware of its carcinogenic properties, and many of those early workers, including some famous scientists working with radiation, succumbed to its effects because of lack of protection.

Ionizing radiations include X- and gamma-rays, electrons, alpha particles and neutrons.

Radiation hazards have been under scrutiny for over 80 years. The chief sources of human data are the populations exposed to whole-body irradiation at Hiroshima and Nagasaki, patients exposed to radiation therapy, and various occupationally-exposed populations such as uranium miners and radium-dial painters. A clear-cut increase in cancer incidence and mortality with increasing dose of ionizing radiation has been demonstrated for many types of cancer in human populations as well as in laboratory animals. The non-threshold concept, which is clearly demonstrated for ionizing radiation, indicates that some degree of risk is associated with any exposure to ionizing radiation. Awareness of the long-term effects of radiation exposure led to development of the 'maximum permissible exposure' concept. Attempts have been made to relate this allowable exposure to the natural ionizing radiation in our environment as a basis for defining a natural level of risk.

There are several natural sources of radiation exposure, including terrestial radiation, cosmic radiation and radiation from radioactive elements in our bodies. Medical applications of radiation, particularly X-rays, are a further source of exposure. Occupational exposures may exceed background radiation by several fold. Occupational exposure to ionizing radiation became of significance only following the discoveries of X-rays in 1895 and radioactivity in 1896. The fact that it can damage living tissue became apparent very quickly. Radiation injuries suffered by luminous watch-dial painters who had inhaled or swallowed radium, were first reported in 1925. At high levels of exposure, acute destruction of bone and bone marrow resulted in death within a few years. The experience of early workers also revealed that repeated doses of radiation that are too small to produce any immediate reaction, may produce cancer many years later.

Types of Cancers Induced

Cancers induced by ionizing radiation are indistinguishable from those occurring naturally, hence their existence can be inferred only on the basis of a statistical excess above natural incidence. Cancer may be induced by ionizing radiation in nearly all the tissues of the human body, although tissues and organs vary considerably in their sensitivity. The types of cancer which show the highest sensitivity to radiation induction are leukemia and breast cancer.

Latent Period

Because of the very long latent periods which may separate exposure to radiation and the development of effects in humans, the true health risk of radiation exposure can be assessed only with extremely long follow-up (30 years or more) of the populations under study.

Effect of Age

Age at exposure to ionizing radiation has an important influence on its carcinogenic effect. For example, the excess risk of breast cancer appears to be highest for women exposed in the second decade of life, when major hormonal changes are taking place. An association between prenatal exposure to ionizing radiation and an increased risk of developing malignancy during childhood has been established, but there remains some question about the extent to which this represents a casual relationship.

Other Variables

Various host or environmental factors may act together with radiation to affect cancer incidence. For example, a cigarette smoker appears to be at greater risk of developing lung cancer from radiation exposure than is a non-smoker.

Current evidence would seem to be against large differences in sensitivity to ionizing radiation within the population.

The carcinogenic effects of ionizing radiation comply with the criteria of causation of Bradford Hill[1]. (See page 173). For example, the association of exposure to ionizing radiation and subsequent deaths from leukemia is strong and consistent (relative risk greater than 20 in the Hiroshima and Nagasaki atomic bomb survivors exposed to 400 rads or more). The strong association is limited to particular sites and types of disease (all forms of leukemia, except chronic lymphocytic leukemia, were increased in incidence in atomic bomb survivors). The temporal relationship, existence of a biological gradient, biological plausibility and coherence criteria are all met.

The history of ionizing radiation is a classic example of recognition of the importance of carcinogenic effects only after the exposure of human populations. This, however, has led to considerable efforts being made to reduce the risk of exposure to ionizing radiation; an example is the radiation control program of the nuclear power industry in Ontario.

2. Vinyl Chloride

Vinyl chloride exposure in the workplace was first recognized as cancer-inducing in 1974 in a branch of a chemical company. This recognition was made because of the occurrence of a small cluster of cases of an unusual form of cancer, a rare liver cancer called angiosarcoma. Only then did scientists appreciate the significance of the finding of a similar cancer, a few years before, in experimental rats exposed to vinyl chloride. Since then, this same type of liver cancer has been reported in workers exposed to vinyl chloride in several countries, including Canada, where it has been reported in Ontario and Quebec.

This 'case study' illustrates the possible value of screening for carcinogens in experimental animals. If action had been taken as soon as the experimental findings had been reported, some workers might have been prevented from developing this form of liver cancer.

Angiosarcomas associated with exposure to vinyl chloride probably take from 15 to 25 years to develop. However, the exposure to the chemical need not be over the whole latency period. Several workers developed cancer 20 or 30 years after a relatively brief but intense exposure (5 months to 3 years). This emphasizes the need for minimizing or, if possible, avoiding completely any exposure to vinyl chloride. Although exposure levels of less than 10 parts per million were considered in the mid 1970s to be difficult to achieve, levels of 0.5 ppm or even less are now routinely maintained in Sweden and the USA. In the USA, production dropped by 25 per cent during the year that stringent controls were put into place. However, production the following year (1975) increased by 37 per cent, thus not only making up for the loss, but exceeding the usual annual increase of around five/six per cent.

As with some other carcinogens, vinyl chloride itself is not cancer producing, but must first be converted by the metabolic processes in the body, especially the liver, to an active derivative. It is this chemically reactive product that damages the liver cells in such a manner as to start the reaction that results ultimately in liver cancer. Although histological changes can be seen in the liver during this long period of development, they are generally not severe enough to be picked up on examination of the worker, nor are blood tests indicative of early changes. It is so far not possible to predict which exposed individuals may be susceptible to cancer induction with vinyl chloride.

We do not have any data on how much exposure is needed to induce liver cancer. It is assumed by many scientists that no threshold level exists for vinyl chloride. This is considered to be the case for all carcinogenic substances.

So far, only angiosarcoma and the more common type of liver cancer, liver cell cancer, have been shown in humans to be associated with human exposure to vinyl chloride. However, in experimental animals, vinyl chloride is also associated with an increased incidence of several other types of cancers. The possibility that vinyl chloride can induce other forms of human cancer should be considered in view of the similarities between the disease patterns in people and in experimental animals exposed to carcinogens. It is to be hoped that no vinyl chloride-induced cancer will occur in those who began working in factories with the new tight controls on exposure established in the last few years. However, we may, unfortunately, continue for another 20 or more years, to see workers who were exposed prior to 1975 or 1976 develop vinyl chloride-associated disease because of the latency period between exposure to a carcinogen and the development of cancer.

Lessons

1. Animal screening would have detected the carcinogenic effects of vinyl chloride.
2. Because vinyl chloride produced a very rare form of cancer, its effect was easy to detect in humans.
3. Once the problem was recognized, it was possible for industry to introduce control measures that resulted in very low levels of exposure to vinyl chloride.

3. Smoking

In this section, we are using smoking data as an example of a carcinogen largely influenced by lifestyle, for which the effects on humans have been well documented.

Smoking can interact with factors in the workplace environment to increase greatly the risk of developing lung cancer. For example, the risk of lung cancer in a person who smokes heavily is almost 11 times greater than in a non-smoker. The risk of an asbestos worker developing lung cancer is about five times greater than that of a person who is not exposed to the substance, while the risk of developing lung cancer when asbestos exposure is combined with cigarette smoking is 53 to one.

Lung Cancer

In Canada, lung cancer is the most important* cancer in men and is rapidly approaching this position in women. There is a continued upward trend in overall mortality rates from lung cancer. However, there is now some indication of a downturn in mortality in males in the 40 to 49 age cohort, which has also shown a decreased incidence of smoking. In females there is no indication of any slowdown in the rate of increase, and the incidence of smoking among females continues to increase.

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*–i.e. showing high mortality because of high incidence, together with a very low cure rate.

There are substantial variations in incidence and mortality internationally, though nearly all countries have seen increases in the rates of disease, some for several years. The marked international variation confirms the importance of environmental and lifestyle factors, as do the changes that occurred in the rates of disease in groups of migrants. For example, those who migrated from Britain to Canada, Australia and South Africa tended to end up with rates intermediate between those they might have been expected to have experienced if they had remained in Britain and those that prevailed in the host country.

The increases that were seen in mortality in every country appeared to follow the increase in tobacco usage, particularly cigarette consumption, after an appropriate latent interval. Several long-term studies confirmed the increased risk of death from lung cancer with use of any form of tobacco, but most specifically, usage of cigarettes. There is a strong dose-response relationship for different cigarette consumption categories. Although the suggestion was first made in the 1930s that the increase in lung cancer rates in men was due to cigarette smoking, studies did not substantiate this until the 1950s, and even then, the association was not generally accepted as causal until the 1960s. The incidence of lung cancer in smokers appears to be unrelated to age, the latency period being the same regardless of the age at which smoking commenced. Studies indicate that the lower lung cancer rate in women is only a reflection of lower smoking levels overall, not a difference in biological susceptibility to the carcinogens in tobacco. Currently, in Canada, cigarette smoking is estimated to account for approximately 80 per cent of the lung cancer in males and nearly 60 per cent in females.

Those who stop smoking appear to have acquired a certain degree of risk at the time they stop and this degree of risk persists, though in comparison with those who continue to smoke, it becomes less with time.

Other forms of cancer related to smoking are: bladder cancer, laryngeal cancer, oral and pharyngeal cancer and gastro-intestinal cancer.

Conclusion

Smoking of cigarettes and other tobacco products is carcinogenic in humans, complying with most of Bradford Hill's[1] criteria of causation. Thus, the association is strong (relative risk 10+ for lung cancer); it is consistent in many studies and countries using different methodologies; the temporality of the association is correct; there is a marked biological gradient or dose response curve, with no evidence of a threshold of effect; it is plausible, consistent with biological knowledge, and is coherent, i.e. does not conflict with the known facts of biology and natural history of cancer. It is, of course, not specific in the sense that many different types of cancers and some non-cancerous diseases are caused by cigarette smoking, though perhaps this is not surprising in view of the multitude of different substances in tobacco likely to be involved. Further, evidence from studies in humans has been hard to come by, though many regard the effect of cessation of cigarette smoking with reduced risk of most smoking-induced cancers, subsequently, as at least partly complying with this criterion.

For lung cancer, cigarette smoking is synergistic with exposure to asbestos and other carcinogens. Similar effects have not been confirmed for other types of cancer, though this possibility should be borne in mind. Currently, in Canada, the average life expectancy of cigarette smoking males is seven years less than that of non-smokers. The lifetime risk of death from cigarette-associated cancers in males (after correcting for other causes of death) approximates to 15 per cent compared to the less than three per cent risk of death from these cancers for non-smokers. Most of this difference is due to lung cancer (12 per cent compared to less than two per cent). Hence, strong endeavours are being made to reduce cigarette smoking, and to attempt to develop cigarettes that are less carcinogenic.

Lesson

The studies of smoking represent one of the best examples of careful epidemiological work showing the close association between a major source of carcinogens and cancer, and the relative failure of public attitude and policy to do anything about it.

4. β-Naphthylamine

A variety of synthetic dyes was introduced into commerce during the latter part of the 19th century. Many, including β-naphthylamine, were based on aromatic amines, which turned out to be powerful carcinogens and induced bladder tumours in hundreds of workers before the situation was brought under control. A salt paste produced in the process was dried on trays and powdered in open mills, thus exposing the workmen to the dusts. With a change in the processing technique, more workers were exposed to the hazard as β-naphthylamine vapour was carried throughout the plant.

β-naphthylamine was first manufactured on a large scale in 1889. During the last decades of the 19th century, large dye works developed in Germany and Switzerland. By 1913, over a hundred cases of occupational bladder cancer were known, and the German chemical industry introduced protective measures. With the outbreak of the First World War, the Allied Countries, cut off from German supplies, began to develop their own industries, and the German and Swiss experience in identifying the hazards of β-naphthylamine production was ignored. Despite an ever-increasing number of cases, no concerted effort was made in Britain to address the problem until after the Second World War.

In 1954, the 'Case' study of bladder cancer in the British chemical industry showed that 10 per cent of the occupational group studied had developed bladder cancer. These workers had been engaged in the manufacture or use of benzidine, β-naphthylamine and α-naphthylamine. It was shown that the risk of one of these workers developing bladder cancer from exposure to β-naphthylamine was 61 times that of a man in the general population. Moreover, the occupational bladder cases occurred at much younger ages than in the general population. The age at onset of bladder cancer was directly related to the age of entry into the occupation. There was much variation in the latent period, the average time of onset being about 18 years after first exposure. Further studies showed that as the dose increased, the percentage of the individuals affected also increased and the latent period was shortened.

There are now data to show that β-naphthylamine in carcinogenic is some animal species. However, it is not β-naphthylamine itself which initiates the process of tumour induction, but a metabolite formed in the liver and excreted in the urine.

The presence, use and manufacture of β-naphthylamine in factories is prohibited in the UK, and its use is regulated in the US. In Ontario, β-naphthylamine is regarded as a known carcinogen to which no exposure should be permitted. In general, it has been possible to substitute non-carcinogenic materials for β-naphthylamine and to avoid its use as a synthetic intermediate.

While pure as well as commercial β-naphthylamine and benzidene induce tumours, α-naphthylamine is a very much less potent carcinogen and there is no convincing evidence that pure α-naphthylamine is a hazard. The industrial hazard which had earlier been associated with the use of commercial α-naphthylamine was, in fact, a consequence of contamination by the β-isomer.

Lesson

This is an example of the failure of industry in one country to take into account evidence developed in another country.

4. CANCER TRENDS IN ONTARIO

One widely-held belief is that the increased use of chemicals and other changes in lifestyle have led to an increase in incidence of cancer. In this chapter we examine the actual evidence[2] of the problems in Ontario. Figures 1-4 on page 153 give an indication of trends in recent years.

Cancer was the underlying cause of death for 13,584 Ontario residents in 1978. It accounted for 22.4 per cent of all deaths in Ontario and was the second leading cause of death in both males and females. (Accidents were the leading cause of death in the young (under 34) and circulatory disease exceeded cancer in those over the age of 35). Cancer was the leading cause of death in women between the ages of 35 and 59, accounting for 44.9 per cent of the deaths in this category. The majority of deaths from cancer in both sexes occurred over the age of 55.

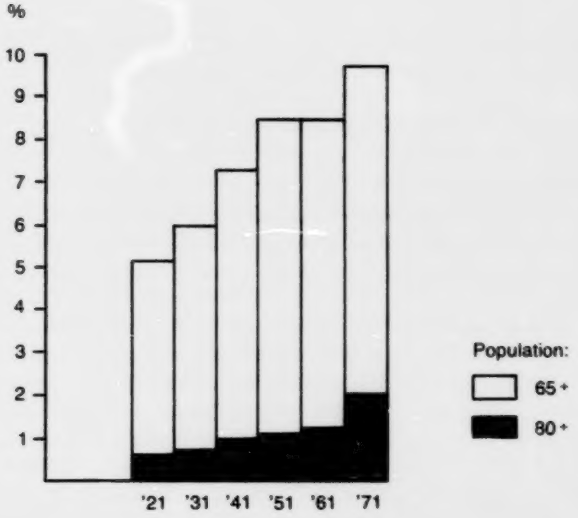
In men, cancer of the lung accounted for the largest proportion of cancer deaths, followed by cancer of the large intestine and prostate. In women, cancer of the breast and large intestine were responsible for the largest proportion of cancer deaths, followed by cancer of the lung and ovary.

Between 1950 and 1977, the age-adjusted cancer mortality rates for males increased, whereas in females mortality rates declined.

Mortality figures for individual sites of cancer have varied. For both sexes, deaths from lung cancer increased at all ages, a change which can be primarily attributed to smoking. The mortality rate from cancer of the lung in females was below that of males. However, in recent years, the rate of increase in the female mortality rate from cancer of the lung has exceeded that of males. In males, mortality from cancer of the stomach declined.

There was no change in mortality from cancer of the bladder, prostate or intestine. In females, mortality rates from cancer of the breast, intestine and ovary showed no change, whereas there was a general decline in mortality from cancer of the cervix and uterus.

The incidence of cancer increases steadily and dramatically with age—males over 80 suffering over one hundred times the death rate from cancer of males under 30. As a result of this strong age effect, the total incidence of cancer in a population will depend to a large extent on the age distribution of the population. Thus, during the first years of this century, life expectancy was limited since many people died of infectious diseases at relatively young ages. The fact that many more people now live longer means that a greater percentage of the population will now die of cancer. The following figure shows the elderly as a percentage of the total population of Canada between the years 1921 and 1971:



Because of the growth of the population in the past few decades, the total number of cancer deaths has also increased. The strong age dependence also means that one cannot usefully compare the incidence of (or mortality from) cancer in different populations unless these have the same proportion of the different age groups. Since this is, in general, not the situation, epidemiologists have devised means of 'age-adjusting' the data. This process involves using the data for each age group (e.g. 40-44, 45-49, etc.) in real populations to compute the 'age adjusted' frequency in a hypothetical reference population. By this means, the cancer experience in different geographical areas, occupational groups and the like can be compared in a meaningful way.

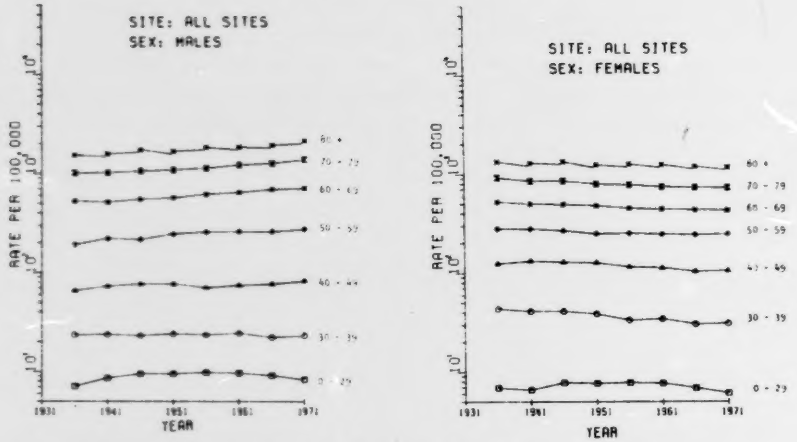


Fig 1. Age group-specific mortality rates for all sites of cancer by sex, 1934-1973.

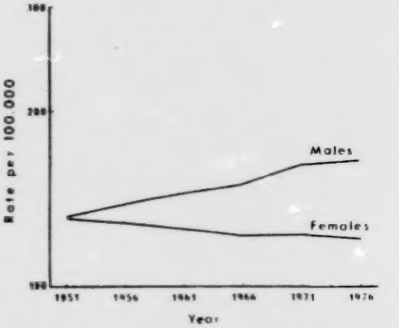


Fig. 2 Age-adjusted mortality rates for all cancer sites by sex, Ontario, 1950-1977. (Age adjusted to the 1961 population of Ontario)

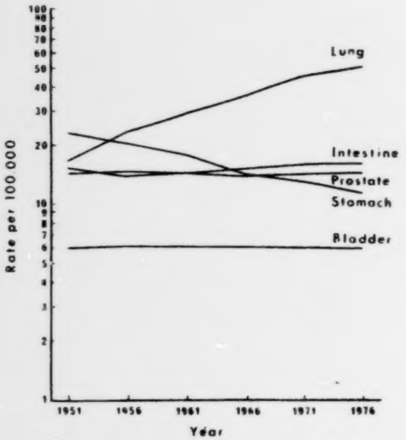


Fig. 3 Age-adjusted mortality rates for selected male cancer sites, Ontario 1950-1977. (Age adjusted to the 1961 male population of Ontario)

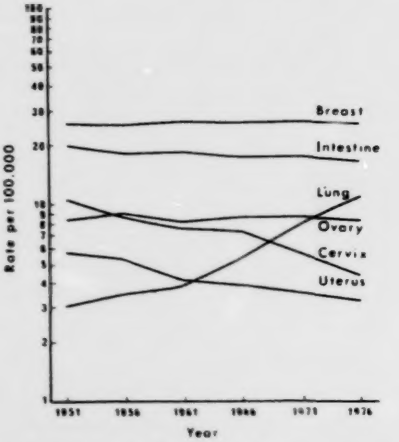
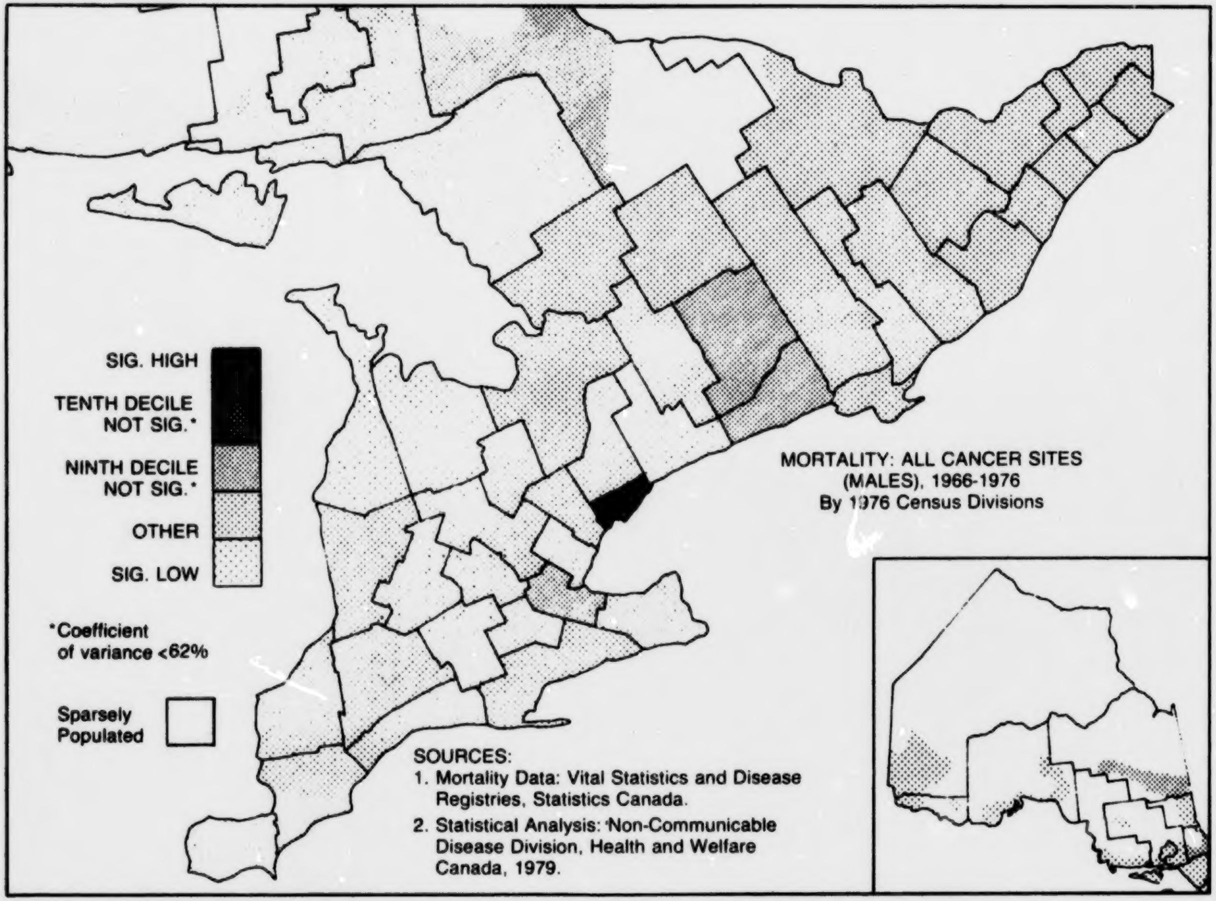


Fig. 4 Age-adjusted mortality rates for selected female cancer sites, Ontario, 1950-1977. (Age adjusted to the 1961 female population of Ontario)

The following maps show cancer rates in Ontario, by census division. The maps show that in some locations there is a greater risk of death from cancer than in others. There is no obvious explanation for this variation. The higher male mortality figures in the Toronto, Hamilton and Niagara Falls regions could be related, in part, to the nature of the industrial work in those areas from which there can be increased occupational as well as environmental carcinogenic exposure. However, such differences between highly industrialized and more rural areas have been noted elsewhere. Most investigators have found that the differences can be primarily attributed to differences in cigarette smoking in the various areas.

Lessons

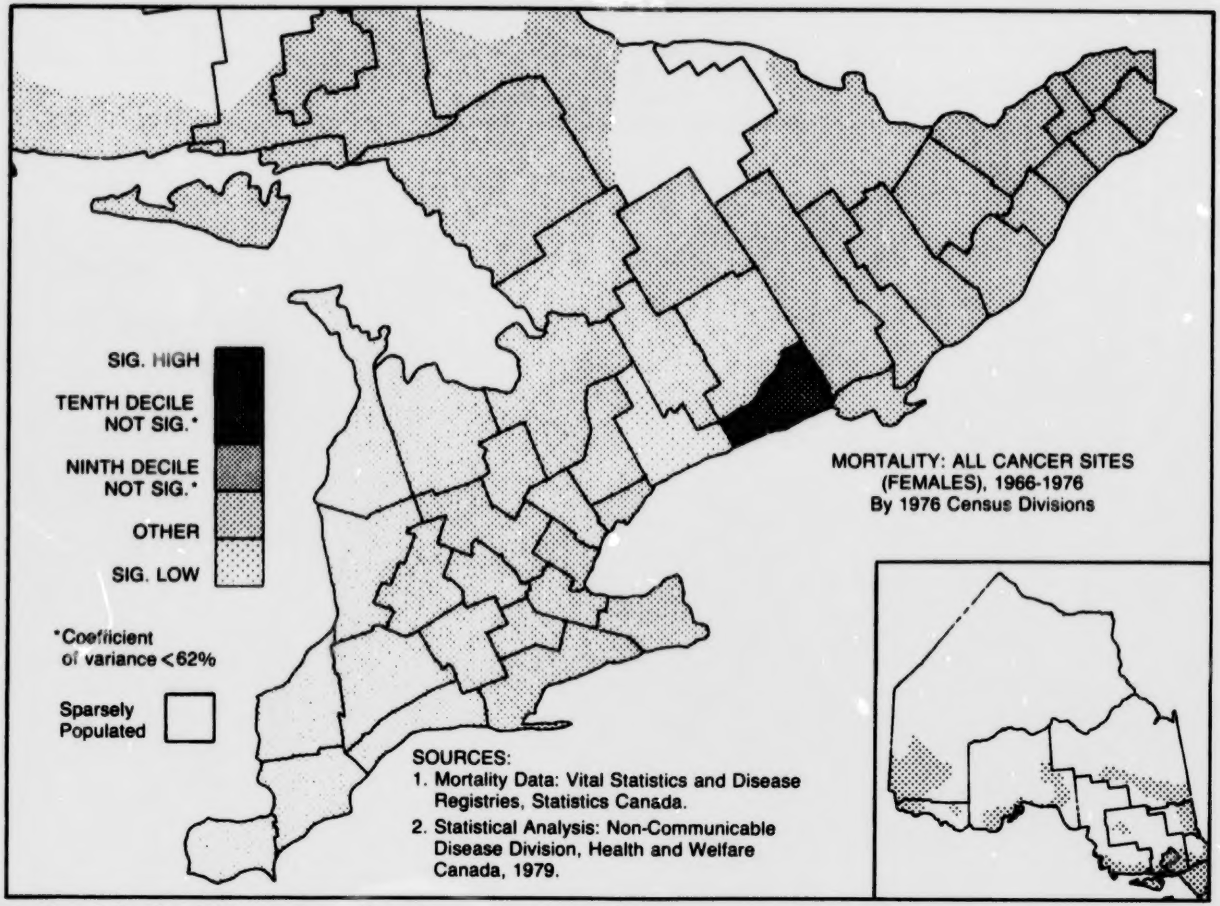
1. The widely-held belief that changes in lifestyle have led to an increase in cancer is valid in Ontario for lung cancer, and is attributable mainly to cigarette smoking.
2. Another major identifiable change affecting the incidence of cancer in Ontario is the increase in the elderly as a percentage of the total population.


SIG. HIGH
TENTH DECILE NOT SIG.*
NINTH DECILE NOT SIG.*
OTHER
SIG. LOW
*Coefficient of variance <62%
Sparsely Populated

MORTALITY: ALL CANCER SITES
(MALES), 1966-1976
By 1976 Census Divisions

SOURCES:
1. Mortality Data: Vital Statistics and Disease Registries, Statistics Canada.
2. Statistical Analysis: Non-Communicable Disease Division, Health and Welfare Canada, 1979.

Produced for the Advisory Council on Occupational Health & Occupational Safety, Ontario, by the Geocartographics Group, Statistics Canada, 1981.


MORTALITY: ALL CANCER SITES
(FEMALES), 1966-1976
By 1976 Census Divisions
SIG. HIGH
TENTH DECILE NOT SIG.*
NINTH DECILE NOT SIG.*
OTHER
SIG. LOW
*Coefficient of variance < 62%
Sparsely Populated
SOURCES:
1. Mortality Data: Vital Statistics and Disease Registries, Statistics Canada.
2. Statistical Analysis: Non-Communicable Disease Division, Health and Welfare Canada, 1979.

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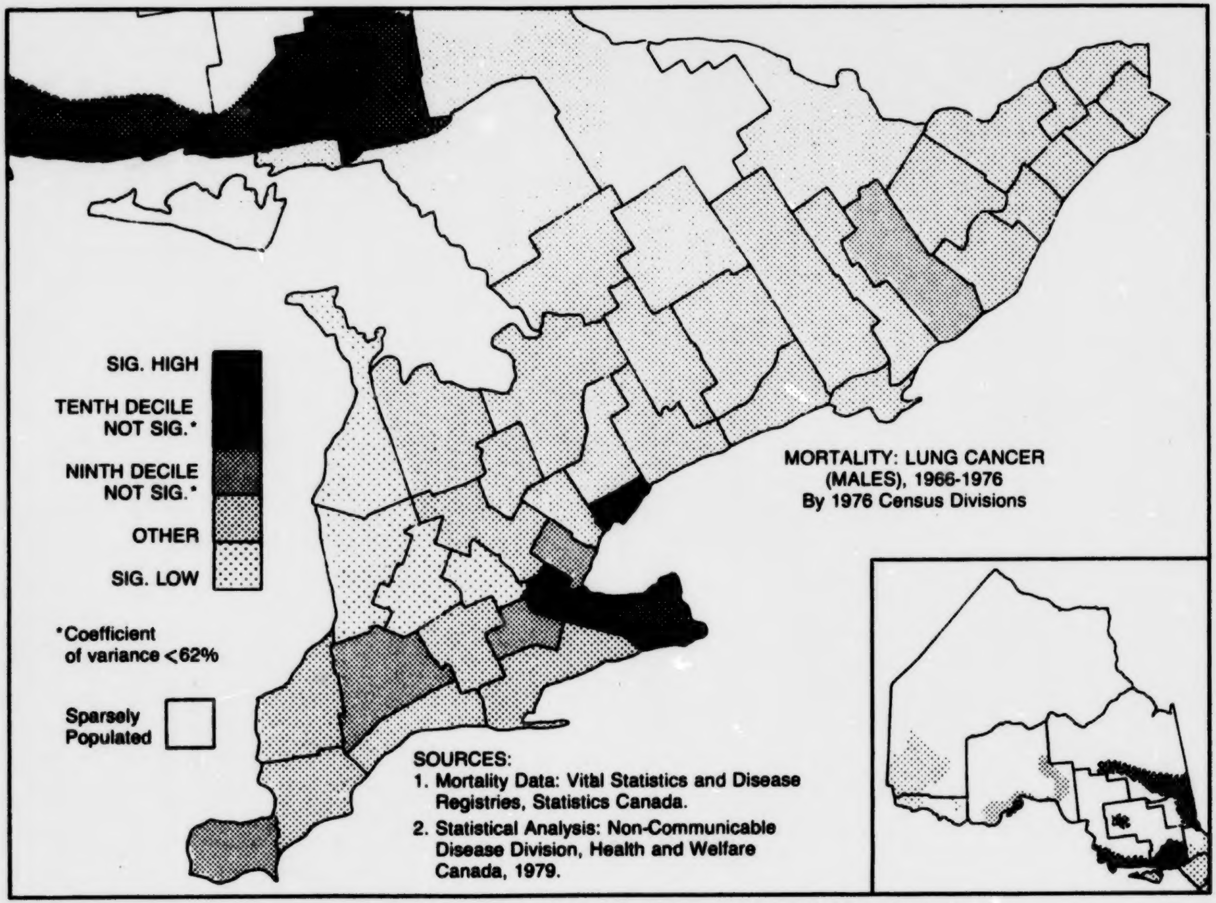
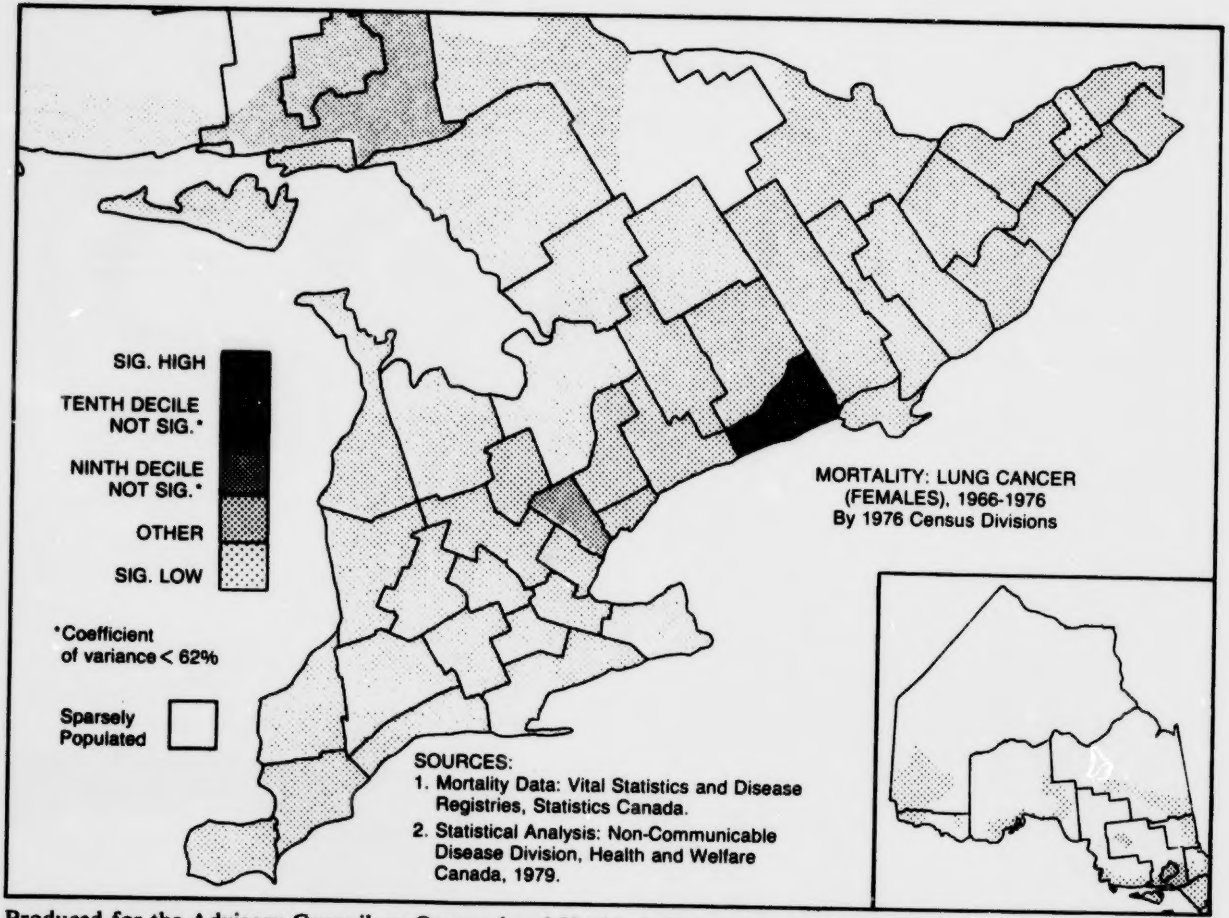

SIG. HIGH
TENTH DECILE NOT SIG.*
NINTH DECILE NOT SIG.*
OTHER
SIG. LOW
*Coefficient of variance <62%
Sparsely Populated

MORTALITY: LUNG CANCER
(MALES), 1966-1976
By 1976 Census Divisions

SOURCES:
1. Mortality Data: Vital Statistics and Disease Registries, Statistics Canada.
2. Statistical Analysis: Non-Communicable Disease Division, Health and Welfare Canada, 1979.

Produced for the Advisory Council on Occupational Health & Occupational Safety, Ontario, by the Geocartographics Group, Statistics Canada, 1981.


SIG. HIGH
TENTH DECILE NOT SIG.*
NINTH DECILE NOT SIG.*
OTHER
SIG. LOW
*Coefficient of variance < 62%
Sparsely Populated

MORTALITY: LUNG CANCER
(FEMALES), 1966-1976
By 1976 Census Divisions

SOURCES:

1. Mortality Data: Vital Statistics and Disease Registries, Statistics Canada.
2. Statistical Analysis: Non-Communicable Disease Division, Health and Welfare Canada, 1979.

Produced for the Advisory Council on Occupational Health & Occupational Safety, Ontario, by the Geocartographics Sub-Division, Statistics Canada, 1981.

5. ASSESSMENT OF RISK FACTORS

Epidemiological studies indicate different rates of incidence for certain types of cancer in different areas of the world. For example, Japan has an extremely low rate of breast and colon cancer and a high rate of stomach cancer. The reverse applies in Canada. Japanese immigrants to North America show, within a generation or two, the cancer incidence patterns characteristic of the North American population. These and related facts have led John Higginson[3] to state that:

> '...it is concluded that these differences (in the incidence of various tumours in different parts of the world) probably represent the proportion of cancers influenced by exogenous factors. The conceptual significance of these observations indicating that 90 per cent of cancers are preventable is obvious.'

This statement has been the subject of considerable misunderstanding—partly through overemphasis of the role of manufactured chemicals and industrial pollution. Higginson[4] has recently clarified the intention of his earlier statement and indicated that in his terms the 'environment' ('exogenous factors') represents the sum total of the milieu in which people live including 'lifestyle factors' such as diet, cigarette smoking, sexual habits as well as more obvious exposure to carcinogenic substances.

The problem of trying to determine the relative importance of exposure to various types of carcinogens is extremely difficult, but is obviously a matter of great practical importance. Among the complexities that must be reckoned with in trying to assess the relative importance of various carcinogens in causing human cancer are the following:

1) there is a latency period of five to 40 years between initial exposure to the agent(s) that causes cancer and the clinical appearance of tumours,
2) except in very extreme cases (see case history on β-naphthylamine), only a small proportion of those exposed to a given carcinogen will develop cancer. The effect of exposure to carcinogens is to increase the probability of tumours developing.

In some circumstances, it is possible to determine the proportion of the disease which can be attributed to a particular factor. This is best done by comparing the incidence of (or mortality from) a given tumour in a population which has been exposed to a particular factor with the incidence (or mortality) in another otherwise matched population, which has not been exposed to this factor. The difference between the two rates will then indicate the amount of the disease than can be attributed to the factor in question. For example, since the incidence of lung cancer amongst smokers is about 10 times higher than that for non-smokers, it is reasonable to conclude that 9 out of 10 cases of lung cancer in cigarette smokers are due to the carcinogenic stimulus of cigarette smoke. It is also reasonable to conclude that one out of 11 would have developed without this factor.

Since a given tumour may develop as the result of more than one carcinogenic stimulus (see Case History on Smoking), it is better to talk about 'risk factors', each of which increases the probability of a tumour developing at a particular site in a particular individual, than to speak of the 'cause of cancer'. An asbestos worker who smokes is exposed to two identifiable risk factors—tobacco smoke and asbestos. From the date of Hammond *et al*,[5] it appears that the risk of a smoker who is not occupationally exposed to asbestos developing lung cancer is almost 11 times that of a non-smoker who is not exposed to asbestos, and that the rate for asbestos workers who do not smoke is 5.2 times that of persons who neither smoke nor are exposed to asbestos, while for those who both smoke and work with asbestos, the risk is 53 times that of the unexposed non-smoker. In this situation and in others, such as bladder cancer, where a number of individual agents are well recognized as risk factors, the sum of the various attributable fractions may easily exceed 100 per cent. This is just an indication of the extent to which a cancer has resulted from the interaction of more than one causal factor.

Finally, it should be clear that, in general, it is not possible to state with any certainty exactly what agents were responsible for the development of a given tumour in a particular individual. The best that can be done is to suggest the relative importance of various risk factors.

In spite of the difficulties involved, various groups have tried to make estimates of the relative importance of factors such as 'lifestyle' (diet, smoking habits and the like) and occupational exposure to the total cancer burden of the general population. The conclusions reached differ widely and the lack of agreement reflects both the difficulty of the problem and the scarcity of the necessary data to provide definitive answers. At one extreme are those like Wynder and Gori,[6] who attribute only five per cent of cancer in males and two per cent in females to occupational factors, while at the other extreme, are those (see for example, the 1978 US NCI, NIOSH, NIES report, reprinted in reference #7) who believe that 20 per cent or more of cancer may be occupational in origin. The papers presented at a meeting devoted to the quantification of occupational cancer, held during March 1981, have just been published.[7] In the United Kingdom, Fox and Adelstein,[8] using the Registrar General's figures on occupational mortality in 1970-72, attempted to answer the question of how much mortality of an occupational group reflects work environment and how much, way of life. Their analysis suggested that, overall, some 18 per cent of the variation in mortality rates between occupational groups was occupationally related—more than 80 per cent of the variation being related to social class. Twelve per cent of the variation in cancer mortality rates appeared to be associated with work.

Given data such as the Ontario cancer rates presented above, it seems reasonable to conclude that the recent development of industrial chemicals and processes has not caused a new epidemic of cancer in the population as a whole. Such a conclusion is similar to one recently reached by Doll and Peto,[9] who reviewed trends in mortality from cancer in the United States from 1933 to 1978. There is, however, one proviso that must be noted here, namely that since the latent period for the development of human cancer is long, the full consequences of a new carcinogenic substance will not be apparent for many years after its first introduction. Thus, it is conceivable that there may yet be a significant increase in cancer due to chemicals introduced in the past 15 to 25 years. Only time will provide a definitive answer.

The conclusion that there is no real evidence for an increase in the age-adjusted incidence of cancer in the general population should in no way be taken as a reason for downgrading the importance of occupational carcinogens. Indeed, it should be clear that in situations in which the combined risks from an occupational factor (e.g. asbestos) and a 'lifestyle' factor (e.g. smoking) are more than additive, removal of *either* factor alone will cause a dramatic reduction of the risk. To go back to the data of Hammond *et al*[5] on smoking asbestos workers, one can estimate that in that particular population with those degrees of risk, removal of the smoking factor *alone* could prevent 79 per cent of the lung cancer, while removal of the asbestos factor *alone* could prevent 90 per cent of the cancer.

Occupational cancer hazards are much greater for small groups of workers who are exposed to relatively high levels of carcinogenic agents, and thus might not be detected in provincial statistics. Procedures are needed which will facilitate the detection of carcinogens in the workplace. In addition, continued industrial innovation results in the introduction to the workplace of several hundred new compounds each year, and policies are needed to ensure that such compounds have been tested for potential carcinogenic hazards.

It must be recognized that, as was shown in the case studies, significant efforts have been made to reduce exposure and these should have an effect, over the course of time, on the incidence of cancer related to workplace exposure.

Lessons

There is no convincing evidence that there has been, at least up to the present time, any significant increase in cancer in the population as a whole, due to chemicals introduced in the last 15 to 25 years. This does not mean that occupational cancer hazards are unimportant, but that they must be dealt with by the detection and control of carcinogens in the workplace, not by monitoring provincial statistics for the general population.

6. CANCER IN THE WORKPLACE IN ONTARIO

The data do not exist to permit a reliable estimate to be made of the percentage of cancer deaths in Ontario which can be attributed to occupational exposure to carcinogens. The only statistics available in this area are those produced by the Workmen's Compensation Board.[10] In assessing the significance of statistics on accepted claims related to occupational cancer, two factors must be borne in mind:

1. The delay in recognizing workplace hazards as being possible causes of cancer, and
2. The fact that the Workmen's Compensation Board figures probably do not reflect the true extent of the problem. Because of the sometimes lengthy latency period between exposure to a carcinogen and the development of cancer, an exposed worker may have moved to another occupation and, as a result, may find it difficult to establish his or her claim. The worker may not even know that he/she has a claim.

During a 35 year period from 1947 through to December 31, 1981, the Workmen's Compensation Board of Ontario accepted 588 claims related to occupational cancer. Four hundred and three of these claims were related to lung cancer. A breakdown of this figure shows 85 related to radon gas, 165 related to nickel sintering operations, 59 related to asbestos fibre dust, 33 related to arsenic, 16 cases related to coke oven operations, 12 cases related to one company (Consumers' Gas) in Toronto many years ago where commercial and domestic gas was developed utilizing coking processes, 27 cases from DOFASCO operations and six from other foundries.

During this same interval, the WCB has accepted 57 cases of sinus cancer related to nickel sintering operations.

Fifty-one cases of mesothelioma related to asbestos fibre dust have been identified.

Nine cases of gastrointestinal cancer have been accepted for compensation as being related to asbestos fibre dust exposure.

Fifteen cases of laryngeal carcinoma have been accepted, ten of which have been related to nickel aerosol exposure in smelting operations and five have been related to asbestos fibre dust exposure.

Forty-three cases of skin cancer have been accepted. These have multiple causation including radiation, exposure to cutting oils, chronic traumatic ulceration, etc.

Five cases of bladder cancer have been accepted. These were related to aniline dyes.

Four cases of leukemia have been accepted. These have multiple causes including radiation and exposure to benzene.

One case of synovial sarcoma has been accepted.

Lesson

To date, the identification of carcinogens has been dependent upon workplace exposure and the subsequent identification of cancer in members of the work force. We are now faced with the challenge of designing a system to control substances which could contribute to the development of cancer, so that the work force need not be exposed. An alternative method of identifying carcinogens must be employed—one which can provide advance warning of a hazard and which is not dependent upon the results of the exposure of a human population.

7. SCREENING FOR CARCINOGENS

Until recently, our limited knowledge of cancer and carcinogens made it difficult to develop approaches that might predict whether a chemical was a potential carcinogen. However, our increased understanding of the mechanisms of carcinogenesis has now made it possible to develop systems for screening new substances as possible carcinogens. Since it is widely accepted that prevention is one of the most important measures for preserving the health of individuals, a key question is: Can these new tests be used to identify potential carcinogens and allow us to prevent inadvertent exposure of the work force?

There are two major approaches that are involved in the screening of carcinogens: short-term *in vitro* screening tests which are relatively cheap and quick to perform and longer-term more expensive animal tests.

1. Animal Tests

a) Long-term Animal Tests

The most reliable and generally acceptable index of cancer-inducing properties of chemicals in humans, next to the study of humans, is the induction of cancer in experimental animals. The basis for the general acceptance is the increasing realization that animals, especially mammals, react to toxic substances very much as humans do. This includes both acute reactions and long-term ones such as cancer development. Even though cancer may take up to one-fourth or one-third of the life span of any species to develop, and involves many steps, the similarities between experimental animals and humans in their reactions to cancer-inducing chemicals are many. For example, of some 30 or more chemicals or chemical mixtures known to induce cancer in humans, only one, arsenic, has failed in long-term animal tests. This high index of reliability makes the long-term animal bioassay for carcinogenicity attractive as the most acceptable test, and generates a comfortable reliance on its predictability. It is only prudent to assume that any chemical that is proven to be cancer-inducing in an experimental animal, may also be so in humans.

However, the animal bioassay, to be reliable, must be done with care and under expert supervision. Since animal species may differ very much in their sensitivity to toxic agents, including carcinogens, and since no single species or group of species resembles the sensitivity of humans more than any other, it is preferable to test the chemical in at least two species.

Also, since cancer may take a long time to develop, sufficient numbers of animals must survive for a sufficient period to allow for this development. Also, since many toxic agents, including carcinogens, may show a sex difference in the development of toxic responses, adequate numbers of animals of each sex should be included.

These are a few of the important factors that must be included in any adequate test for cancer development. This necessitates high quality animal facilities, highly competent pathologists familiar with cancer in animals as well as in humans and careful long-term supervision of the animals under hygienic conditions.

These and other requirements have been outlined as guidelines by the National Cancer Institute[13] in the USA. These guidelines have indicated to industrial and academic centres what constitutes a reliable bioassay procedure and have had an important influence in setting standards.

Unfortunately, the requirements are such that the present cost to test a single chemical may be from $250,000 to $500,000. With this cost factor and with a time period of about two and one-half to three years before an answer is obtained, the importance of the short-term tests becomes evident.

It has been shown in many studies that inert fibres such as asbestos and glass wool will induce mesotheliomas of the pleura or the peritoneum when injected into suitable experimental animals. It must be emphasized that unlike most of the 'usual' chemical carcinogens, these remain in the tissue for a long period of time. The problems relating to the regulation of cancer inducing fibres must clearly be different from those relating to the regulation of chemicals that have a relatively brief sojourn in the body.

b) Short-term Animal Tests

Because of the similarities in the toxic responses of humans and animals, it is desirable that tests for potential carcinogenicity be as closely related as possible to the end stage, cancer. This can be done by the use of an early reaction of an animal to a potential carcinogen and one that consistently precedes the appearance of cancer. So far, only very few such tests have been proposed.

The end-points in these are damage to DNA induced by a potential carcinogen, the repair of the DNA following such damage or the induction of altered cells that can be stimulated to grow and that are precursors for later steps in cancer development. These are largely underdeveloped. They have many attractive features, including the cost that is not much more than that involved in *in vitro* tests using bacteria or cells in culture. These short-term tests in intact animals, especially the one involving altered cells, might prove to be extremely useful for following the development of chemicals that in one form may be mutagenic but can be modified to eliminate the mutagenic capacity. In addition, the use of short-term animal tests offers a comfortable bridge between the *in vitro* tests, which are very difficult to relate directly to cancer, and the induction of cancer.

2. Short-term In Vitro Tests

a) The needs

As mentioned above, conventional animal carcinogenicity assays are expensive, laborious and time consuming. Since there are large numbers of untested chemicals currently in use and many new ones are introduced each year, the development of so-called 'short-term' assays that can detect potential carcinogens has been a matter of great interest. Although the concept is little more than a decade old, dozens of tests have been proposed.

b) The 'concept'

Essentially, all current short-term tests have as their basis some means of detecting damage to DNA in a test organism. The organisms employed range from bacteria, through yeast and cultured mammalian cells, to rodents, while the biological 'end-points' used to detect and quantify DNA damage involve mutation, breakage of DNA, endogenous repair of DNA damage by the test compounds, chromosome damage, etc. It is well established that many carcinogens must be metabolized before they damage cellular constituents. Since bacteria and many cultured mammalian cell lines lack the enzymes required for this process, preparations from mammalian liver are frequently added to provide for 'metabolic activation'. Alternatively, 'host-mediated' assays may be used in which test micro-organisms are injected into an animal (which is exposed to the test compound) and, after a suitable period, recovered and assayed for mutations. Various test systems and the end points involved are shown in the following table. Detailed consideration of these tests has been presented by the International Agency for Research on Cancer[11] and by Weisburger and Williams[12].

'Organism'	*Metabolic Activation*	*End Point*
Bacteria:		
Salmonella typhimurium (the 'Ames Assay')	Liver S9 preparation	– reverse or forward mutation
Escherichia coli	Liver S9	– reverse or forward mutation
Fungi:		
Saccharomyces cerevisiae (yeast)	endogenous	– gene mutation – gene conversion
Neurospora crassa	endogenous	– gene mutation – gene conversion
Mammalian cells:		
[in long term culture] eg. CHO [Chinese hamster ovary]; L5178Y mouse lymphoma; Human fibroblasts	Can be supplied by Liver S9	– gene mutation – DNA repair – *in vitro* sister chromatid exchange – transformation (except human cells)
Primary hepatocytes	endogenous	– DNA repair
Intact animals		
rat liver	endogenous	– pre neoplastic enzyme markers
rodents	endogenous	– *in vivo* sister chromatid exchange

c) Some Examples

While it is not the purpose of this document to provide a comprehensive account of the short-term assays currently available, a few examples will illustrate the development and application of some of the important tests.

(i) *Salmonella/S9 assay (Ames assay)*

The strains of bacteria used in the Salmonella/S9 assay are mutants of Salmonella typhimurium, which were developed by Dr. Bruce Ames and his colleagues at the University of California, Berkeley. These test strains are unable to synthesize an essential amino acid called histidine and, therefore, will not multiply and grow into visible colonies unless exogenous histidine is provided in the medium. However, these bacteria can revert to histidine independence through mutation. Mutagenic chemicals increase the rate of mutation and, hence, increase the number of bacteria that are able to grow into visible colonies. It is worth noting that these test strains have been developed so that they will be very sensitive to mutagens. In addition to the original carefully chosen mutation to histidine dependence, additional mutations have been added which a) block DNA repair, b) increase the permeability to large molecules, and c) in some strains the pKM101 plasmid has been added to increase the amount of mutation produced by a given amount of DNA damage.

Since, as noted above, many carcinogens are not active until they have been metabolized by enzymes found in animal tissues but not in bacteria, it is necessary to add appropriate animal enzymes to the test plates. This is done by use of the 'S-9 fraction' from rat liver. A useful feature of this assay system is provided by the existence of strains which respond only to particular classes of mutagen and are totally unresponsive to others.

The Salmonella/S9 assay has been subjected to very extensive validity studies and there is general agreement that it works well with strong carcinogenic 'initiators', but may give false negatives with some other carcinogens such as organochlorine compounds, azo compounds and carcinogenic hormones. The test also gives 'false positives' with some compounds which are not considered to be carcinogenic.

Commercial laboratories currently quote about $1,000 for the thorough testing of one substance in the Salmonella/S9 assay. The time required is less than one week.

It is worth noting that the same strategy, including the addition of S9, can be used to detect mutation in cultured mammalian cell lines. However, somewhat longer times are generally involved.

(ii) *DNA repair in primary hepatocyte cultures*

Hepatocytes (i.e. liver cells) are easily prepared from the liver of animals such as rats. These cells remain 'alive' for several days but do not grow and divide. Nevertheless, they offer advantages as short-term test 'organisms' since they contain many of the mammalian carcinogen-metabolizing enzymes and, unlike the situation that obtains in S9 preparations, these enzymes are in their normal cellular environment. Thus, hepatocytes are able to 'activate' a wide range of carcinogens so that they damage DNA. Other enzymes in the hepatocytes recognize DNA damage and begin repair processes which result in the physical removal of much (but not all) of the damage and the subsequent resynthesis of the DNA chain from low molecular weight building blocks. The repair process can readily be detected if one of these building blocks (thymidine) is radioactively labelled and supplied in the medium. Cells whose DNA has been damaged and at least partially repaired will be radioactive. The DNA of unexposed cells will not be radioactive since it, being undamaged, is not subject to 'removal: resynthesis' repair. This assay has been less extensively validated than the Salmonella assay, but appears at this stage to be very useful at least in a qualitative sense. The cost of the repair assay would be a few thousand dollars per compound and the time involved may be one week (if scintillation counting is used) or several weeks if autoradiographic techniques are used.

(iii) *Sister chromatid exchange*

This assay measures the reciprocal exchange of material between the two chromatids (strands) of a mammalian chromosome. Such exchanges (which can be induced by radiation and mutagenic chemicals) are readily detected by well established cytogenetic procedures. Sister chromatid exchange can be measured either in established cell lines *in vitro* or in intact animals whose bone marrow or lymphocytes can then be examined. (Indeed, the use of blood lymphocytes makes it possible to determine the frequency of sister chromatid exchanges in cells from humans who have been exposed to radiation or chemicals).

Unfortunately, neither the molecular basis for sister chromatid exchanges nor their exact relevance to mutagenesis or carcinogenesis has been established. Such exchanges are, however, generally interpreted as a consequence of damage to DNA and, thus, an indication of exposure to potential carcinogens. Because of the need to score large numbers of cells under the microscope, this test takes several weeks and costs several thousand dollars per chemical.

d) Current Status

Short-term tests are still at a stage of rapid development and improvement. It will be clear from the examples presented above that compromises are made in devising such assay systems. Those assays which involve bacteria or cultured mammalian cell lines have the advantage of a fast and easily detected end-point, but are far removed from the normal pharmacological processes which take place in an intact animal. While addition of S9 preparations provides many of the relevant enzymes, it does not provide the full repertoire of mammalian biochemistry. The *in vivo* test systems also have limitations since they depend upon the active carcinogen getting to and damaging the tissue which is later to be examined, e.g., liver in the case of the assay employing 'pre-neoplastic' enzyme markers or bone marrow for the *in vivo* sister chromatid exchange assay.

Nevertheless, even at this stage, intelligent use of short-term tests can offer a significant degree of protection to workers who are to be exposed to new chemicals. With the present state of the art, one can anticipate that most (perhaps 80 per cent or more) of strongly carcinogenic materials can be detected. While it is to be hoped that the predictive value of short-term assays can be improved, the detection of something like four out of five carcinogens amongst new chemicals in the workplace would represent a substantial improvement over the current situation, where such materials are largely unregulated.

e) Short-term Tests in Human Population Monitoring

(i) *Urine Mutagenicity*

The foregoing section has reviewed the use of short-term assays as a means of screening chemicals for potential carcinogenic or mutagenic hazards to humans. Another use for some of these assays may also prove to be of importance in occupational settings. This involves monitoring human urine for mutagenic activity, or human cells for chromosome damage.

The Ames assay provides a sensitive means of detecting and quantitating the presence of mutagens in the urine of humans. The assay was first used in this way to show that smoking resulted in urinary mutagens (which may well be responsible for the excess bladder cancer seen in smokers). Similarly, mutagens have been detected in the urine of rubber workers and cancer chemotherapy nurses (who handle cytotoxic and carcinogenic drugs). The costs of the test on urine are roughly the same as for pure chemicals and depend in part on the number of strains to be used. In addition, the mutagenic material from urine must be concentrated using non-ionic resins. In such cases, urinary mutagenicity provides direct proof that human tissues are being exposed and gives at least a rough measure of the level of exposure. Further, in such situations, monitoring of urinary mutagens provides a means of assessing the success of any measures introduced to decrease exposure. It should be noted that one cannot expect all mutagens to which humans are exposed to accumulate in the urine since some will be so reactive they 'disappear' completely before there is time for excretion, while others may be metabolized completely to non-mutagenic products before they appear in the urine or may be excreted by other routes. Even in situations in which mutagenic activity is excreted in the urine, it will be cleared from the body fairly rapidly so that sampling times must be chosen judiciously. Then too, there are the inherent limitations of the assay which make it relatively insensitive to some chemical classes of mutagens. Thus, the absence of urinary mutagenic activity does not necessarily mean lack of exposure. The important point is that the presence of urinary mutagens is clear and unequivocal evidence for exposure. Much work is currently being done to assess the potential of such assays in occupational settings.

(ii) *Cytogenetics*

A second approach utilizing material from humans is cytogenetic determination of chromosomal damage. The cells employed are lymphocytes, which can be cultured from blood samples. Thus, the test cells are obtained directly from humans and increases in damage can be attributed to exposure to chromosome-damaging agents. Three end-points have been used: 1) chromosome aberrations, 2) micronuclei (derived from fragments of chromosomes) and sister chromatid exchanges (see previous section). Cytogenetic studies have shown an increase in chromosome damage in heavily exposed vinyl chloride workers and in humans exposed to ionizing radiation. At least in the latter case, it is established that increased chromosome damage in a population is indicative of an increased cancer risk for that population. However, the extent of cytogenetic damage in a given individual *is not* a predictor of the risk of cancer for *that individual*. Again, it is not to be expected that all potential carcinogens will cause cytogenetic changes in lymphocytes. The utility of these assays in occupational settings is currently receiving considerable attention. Chromosome aberrations are most often unstable and the abnormal cells are gradually lost from the peripheral blood circulation with time. For this reason, 'excursion' exposures require immediate follow-up with sample collection (within 24 hours of exposure). Chronic exposures probably could be detected at any time after sufficient exposure.

Cytogenetic studies are expensive since even to detect a substantial difference in chromosome damage between an exposed and an unexposed population requires at least several dozen individuals in each group; estimates range as high as $1,000 per individual examined.

(iii) *Induced Mutations*

Lymphocytes can also be used to assess human exposure to mutagens by determining biochemically the frequency of cells which are resistant to certain drugs. (In normal humans the frequency of drug-resistant lymphocytes is low: exposure to mutagens such as anti-cancer agents causes a marked increase in resistance and it may be possible to use the frequency of drug-resistant cells as an index of exposure). This technique offers the promise of complementing the measurement of gross chromosomal damage provided by the cytogenetic assays described above with information on more subtle effects on particular genes. So far, the procedures used to estimate drug resistance are laborious and, as a result, the costs are high.

(iv) *Sperm Abnormalities*

In animal semen, the frequency of sperm having abnormal shapes is known to be increased by exposure of the animals to some (but by no means all) mutagenic and carcinogenic compounds. Thus, we have another readily available source of human (male) cells which can be scrutinized to try to determine the consequences of exposure of men to a particular environment.

Sperm samples can also be used for the 'fluorescent Y' chromosome test. Normal sperm contain either zero or one Y chromosome and the presence of sperm with two Y chromosomes is indicative of 'non-disjunction' (i.e. failure of the mechanism which normally ensures that one of each pair of newly replicated chromosomes goes to each daughter cell). This process represents a different type of genetic problem from mutation and chromosome breaking.

3. Promoters

There is, at present, no generally accepted way of screening for promoters, either with animal or short-term tests. It is, therefore, important that research be encouraged in this area.

Lessons

Since prevention is one of the most important measures for preserving the health of individuals, a major issue is how best to identify potential carcinogens and promoters and prevent inadvertent occupational exposure. The most reliable tests are still those conducted on animals. Intelligent use of short-term tests offers an attractive, faster and less expensive alternative.

However, these tests have only been developed very recently and new ones are still appearing. Their strengths and weaknesses are still not fully appreciated, and practical experience with them is still quite limited.

8. SUMMARY OF TESTING REQUIREMENTS

Past experience has shown that a small fraction of the chemicals introduced into industry have been carcinogenic. There is no reason to expect that this situation will change unless deliberate interventions are made. All reasonable steps should be taken to minimize the chance that workers will be exposed to new chemicals whose carcinogenicity will be appreciated only after 20 years or more, when cancer appears in the work force. Ideally, extensive animal and short-term tests would be required. Properly conducted, such assays would detect most, but certainly not all, potential carcinogens. However, as stated above, capacity for animal testing (even if the necessary funds could be provided) is inadequate. We must, therefore, fall back upon a battery of short-term tests, recognizing that this strategy should detect most strong carcinogenic initiators, but will be less effective than comprehensive animal tests. As additional short-term tests are developed that increase the range of carcinogens which can be detected, these should be incorporated into the required battery.

1. In Vitro Short-term Tests

We recommend that, as a minimum, two different short-term tests be required. In general, we would expect one of these to be an assay for point mutations in bacteria or a simple eukaryotic organism like yeast (with and without an added activation system) and the other to be an assay which would detect chromosomal breakage or rearrangement in cultured mammalian cells (again with provisions for metabolic activation). Inclusion of other assays such as those for DNA repair will often provide additional useful information. Specific assays should be selected with due regard for the performance of the assays with compounds analogous to those being tested.

We recommend further that these tests be carried out on commercial samples of chemicals rather than (or in addition to) tests on purified preparations since there is abundant experience to show that impurities, rather than the major constituent, may be responsible for the carcinogenic properties of industrial chemicals. Since the whole area of short-term testing is evolving rapidly, we also recommend that the requirements for the use of such tests be reviewed by the ministry every three years.

New chemicals which are closely related to others that are already in use should not be exempted from the testing requirements recommended above. Since isomeric pairs of organic compounds can differ very widely in their properties (e.g. β-napthylamine and benzo(a)pyrene are both powerful carcinogens while their isomers [α-napthylamine and benzo(e)pyrene] are weak or non-carcinogens), we recommend that tests be required on all new organic compounds.

2. Long-term Animal Tests

Animal bioassays must be conducted with care and under expert supervision. We recommend that such tests be performed in two species, using adequate numbers of animals of each sex. We recommend that the requirements outlined by the National Cancer Institute (USA)[13] be followed, as constituting a reliable bioassay procedure.

3. Advisory Committee

It is not possible to make arbitrary rules to deal with all possible outcomes of test results. For example, what should be done with a chemical which gives, say, a positive result in a bacterial mutagenicity assay but negative results with *in vitro* chromosomal tests and in animal cancer bioassays? In some cases, it may be clear that the probability of risk to humans is so low that the substance should be regarded as non-carcinogenic. There may be need for an advisory committee to examine the results obtained with such compounds and to recommend the category into which they should be placed.

9. PRINCIPLES OF EPIDEMIOLOGICAL SURVEILLANCE

Evidence as to whether a substance is carcinogenic or not can be derived, as this report indicates, from a number of sources. Epidemiological data from human studies have been an important source of information in providing evidence on the carcinogenicity of a number of substances encountered in the occupational environment. Indeed, classically, the first studies which identified the risk to humans of occupational exposures arose from the application of the epidemiologic method.

Epidemiologic evidence can be obtained through three broad approaches. Each of these varies in terms of the ease with which the studies can be carried out and the strength of the evidence. The approaches involve:

1. Evidence derived from descriptive studies of the occurrence of cancer in humans in relation to time, place and person.
2. Evidence obtained from analytic epidemiologic studies of the case-control or cohort type.
3. Evidence obtained from well-conducted intervention studies in epidemiology, especially utilizing the methodology of the randomized controlled trial.

1. Descriptive Epidemiologic Studies

Studies of this type are often called 'hypothesis derivation studies'. In their simplest form, an observation is made that a cluster of cases is occurring which general experience would suggest to be unusual. For example, although the carcinogenicity of vinyl chloride was first established through animal studies (see Case History), the significance of these observations was not appreciated until a physician noted a cluster of cases of a rare tumour (angiosarcoma of the liver) in a group of workers from one particular plastics manufacturing plant. A number of similar examples can be given; thus, the first clue may come from the observation of 'alert clinicians'. More precise descriptive studies come from comparisons of the incidence of (or mortality from) cancers at particular sites, occurring in different countries or in different areas or time periods within countries. Comparisons of incidence demand an established population-based cancer registry; comparisons of mortality require an established vital statistics system. Providing the necessary data are supplied, such comparisons can often be extended to the incidence in or mortality of different types of individuals, most obviously on the basis of sex, but also on the basis of race or colour. In the last decade in Canada, such descriptive studies have been placed on a more formal basis whereby the incidence and mortality of cancer is being monitored on a census district, or county level. Already, such studies have indicated unusual occurrences of cancer that might have an occupational basis.

2. Analytic Studies

In recent years, case-control and cohort studies in epidemiology have been brought to a high state of precision. In cohort studies, individuals exposed to a factor considered likely to increase the risk of disease are followed forward in time with a comparable group of non-exposed individuals as a control. The incidence of cancer (or less satisfactorily, the mortality from cancer) is directly compared between the two groups. Various modifications of this approach are possible. Thus, if records are available of complete groups of individuals exposed to a factor from some time in the past, then it is possible to reconstruct the history of this cohort of individuals and analyse incidence and/or mortality of cancer up to the present time. Such an approach may have a number of advantages, both in terms of lesser expense and more timely ascertainment of results, particularly in cancer with a long latent period to be expected from first exposure to development of the disease. It may also be subject to a number of different biases, particularly if there is doubt on the extent to which the original set of records is complete. It may also prove difficult in both historical cohort studies of the types just described and standard cohort studies with follow-up from now to the future to establish an appropriate control group for comparison purposes. In a number of occupational studies, the experience of the general population has been used for comparison, but to the extent that the exposed group differs from the general population in factors other than the exposure of interest, the resulting finding may be misleading.

In case-control studies, the point of departure is the diagnosis of the case of disease. Generally through the interview method, a detailed history is then obtained of lifetime exposure to the factors of interest, and comparison made with comparable individuals free of disease who may be drawn from hospital or general population groups. If the case series is representative of the general population, the control series should be also. This method, though more economical than the cohort approach, is subject to biases of errors of recall. Particularly under some circumstances applicable in the occupational situation, it is possible for individuals who have developed cancer to recall more readily exposure to possible factors of interest as causes, than it is for control subjects to do so. Recall bias of this type has to be specially guarded against when extensive publicity surrounds a factor considered likely to be at risk for occupational cancer.

In general, in spite of its expense, the cohort approach has been preferred to the case-control approach for occupational studies. The main reason has been the ready availability of groups of exposed individuals whose experience has been reconstructed up to the present time. In a number of instances, for example, risks of asbestos, the findings from such historical cohort studies have subsequently been confirmed by the more standard cohort approach. However, increasingly, it has been appreciated that with common cancers and with the need to identify the extent to which different factors may be responsible for their etiology, the case-control approach may have many advantages. Thus, in one interview, it is possible not only to obtain a detailed occupational history, but a detailed smoking history and a detailed history of exposure to other possible risk factors, such as alcohol. Such data are rarely available in a cohort study, even in one set up in the classic mode prospectively. Indeed, because of the possibility that exposure to risk factors may change, for a classic cohort study to provide as much data as a case-control study in terms of different exposures, multiple interviews at different times are essential. This substantially increases the expense and few studies of this type have been performed. Further, with the availability of record linkage approaches, it has been appreciated that the cohort approach may enable some suspect risks to be identified in what becomes a hypothesis-seeking exercise with case-control studies utilized as the hypothesis-testing definitive study. The ready availability in Canada of facilities for record linkage of persons at high risk (see section Epidemiologic Surveillance of Persons at High Risk for Cancer) is likely to facilitate this type of approach materially in the future.

3. Intervention Studies

In general, the randomized controlled trial is accepted as having the least bias and provides the clearest evidence of whether a factor is, or is not, causal. However, for obvious reasons, it is virtually impossible to do such a study in the field of occupational health. Thus, even with the introduction of a new chemical, it is extremely unlikely that it would be possible to randomize individuals to be exposed, or not exposed, to it. Hence, a classic etiologic experiment cannot be performed. Nevertheless, it is possible that this approach may be increasingly used in the occupational situation in a manner which may help to confirm the importance of occupationally encountered risk factors. With a number of potential prophylactics against cancer being available, and with the need that their value be established using randomized controlled trials in individuals at high risk, it seems quite possible that a number of studies evaluating the use of such prophylactics in the occupational setting will take place in the next few years. Studies of this type, if they confirm the efficacy of a prophylactic, could be regarded as also providing further evidence of the importance of causal factors if the prophylactic was designed to counteract directly the effect of the suspected causal factor.

Criteria for Causality

A number of authors, but most particularly Bradford Hill,[1] have identified the criteria which permit the assumption of causality from epidemiological evidence initially being restricted to identified associations. These criteria are as follows:

Strength of the association (relative risk)
Consistency of the association
Correct temporality of the association (i.e. exposure precedes disease)
Biological gradient or dose response relationship
Plausibility of the association (i.e. consistent with biological knowledge)
Coherence of the association (i.e. it does not conflict with the known facts of biology and the natural history of the cancer)
Specificity of the association (i.e. the factor is associated with one disease) Such a requirement is not an absolute one; indeed, it may not be found for materials including a large number of different carcinogens, for example, tobacco smoke.
Experimental evidence (i.e. evidence derived from a controlled clinical trial.) Although we have indicated above that such evidence may be impossible to come by in the occupational setting, an indirect approach to this can be found when exposure to a factor is removed in an occupational group and the risk of disease falls after an appropriate interval.

Lesson

Epidemiological data from human studies have been, and will continue to be, an important source of information about risk factors.

10. EPIDEMIOLOGICAL SURVEILLANCE OF PERSONS AT HIGH RISK FOR CANCER

While epidemiologic studies have been of crucial importance in detecting hazardous substances in the workplace, it is to be hoped that in the future there will be much less reliance on human exposure data in the identification of carcinogens. However, it is unlikely that screening procedures will be devised which will detect all carcinogens. Also, there could be categories of substances for which there is some suspicion, insufficient to justify their treatment as carcinogens, but justifying their careful surveillance.

The Advisory Council on Occupational Health and Occupational Safety[14] has emphasized the need for exposure records for workers who have suffered a unique exposure to a dangerous or potentially dangerous environmental agent. The questions arise as to how such individuals can be kept under surveillance and how it can be determined whether or not they are indeed at increased risk.

The primary mechanisms for such surveillance are already in place in Canada, comprising provincial cancer registries established in each province that regularly submit their data to Statistics Canada and registrations of all deaths for which copies are submitted to Statistics Canada by provincial registrars of vital statistics. The death certificates have been consolidated into files accessible for computerized record linkage back to 1950, and the National Cancer Reporting System includes information on registrations with cancer from 1969 on. Record linkage procedures have been developed within Statistics Canada in collaboration with the NCIC Epidemiology Unit that facilitate inexpensive rapid computerized record linkage of incoming files with these two cumulative files of outcome (cancer registration or death certificate information). Cancer incidence and mortality rates among exposed individuals can thus be compared with the rates observed in unexposed individuals (whose files have been input at the same time) or with the nationally reported rates. This system has already been used for a general assessment of occupational mortality and cancer incidence in Canada using the Unemployment Insurance Commission file for 1966-71 and for other studies of potential occupational hazards and non-occupational hazards such as exposure to ionizing radiation.

The basic requirement for utilization of this existing system is that those to be placed under surveillance must be fully identified in the file to be subsequently used for record linkage. Although identification by Social Insurance Number, which should always be available for occupationally exposed persons*, does provide the means to access personal identifying information through linkage with the Social Insurance Number master file, it would be preferable if the file combined Social Insurance Number with full personal identifying information because Social Insurance Numbers are not currently included on health records and will not be found on death certificates or many cancer registrations. Indeed, if the recommendation in the Report of the Commission of Inquiry into the Confidentiality of Health Information on the Unique Personal Health Identifier is accepted, the Social Insurance Number will not be included on health records. Thus, the Social Insurance Number alone cannot be used for record linkage purposes, personal identifying information having to be used instead.

The items of personal identifying information required include:

—full name with any name changes, particularly for women;
—full date and place of birth;
—mother's maiden name (if available);
—sex;
—marital status (if available);
—town or city and province of last known residence;
—Social Insurance Number;
—Health Insurance Number.

Exposure information should be as detailed as possible while details of prior exposures to other potentially hazardous occupations would also be desirable. If the exposure is believed likely to induce lung cancer, quantitative smoking information is highly desirable.

The other requisite for such surveillance is the continued existence of provincial cancer registries if the exposure is believed likely to have been carcinogenic. The Ontario Cancer Registry has itself been established by record linkage, initially manual and now computerized using routinely available sources of medical information. Unfortunately, in recent years, the registry has been somewhat starved of resources and, thus, although for the rest of the country cancer incidence is available up to 1978 and will shortly be available for 1979, data are only available for Ontario up to 1971, though it is hoped that data through to 1976 will shortly become available. The registry was initiated with the Ontario Cancer Incidence Survey for 1964-66. Because of the great importance of the registry, both in terms of identifying potential hot-spots using descriptive epidemiology and of providing the end-point of studies of workers under surveillance through computerized record linkage, it is essential that the appropriate resources be made available to the Ontario Cancer Treatment and Research Foundation to ensure the registry's continuance. Indeed, because the foundation has a number of responsibilities, it might be felt appropriate to ensure that its budget include, as a line item, sufficient funds to ensure continuation of the registry so that it does not suffer from competition for funds for cancer treatment activities.

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*–until such time as a unique personal identifier other than the Social Insurance Number has been developed to facilitate the linkage of all records relevant to occupational health and safety.

Because of the mobility of the Canadian population, and the desirability of ensuring that workers who migrate from Ontario continue to be followed if they have been placed at risk and are under surveillance, it is important that the record linkage be conducted with the national rather than the provincial files. Ontario is a beneficiary from the inclusion of the Ontario registry in the national system in having access to follow-up data from other registries as well as being the largest single contributor.

In order to establish whether or not the group under surveillance is at increased risk, record linkage of the file of exposed and, preferably, other non-exposed but comparable individuals would be performed at regular intervals with the two national data files (cancer registrations and deaths). Even if cancer incidence is the only end-point of interest, linkage with the death records is essential in order to determine the person-years at risk and to identify those who are no longer at risk because of death from other causes. Further, for non-cancer causes of interest that might be attributed to hazardous exposures, death from these conditions is, at present, the only outcome measure which could be evaluated using this system. With adequate identifying information, it can be assumed that if a link has not been made with one or other of the two files, the individual is still alive and has not developed cancer. There are two possible sources of error. One is failure because of paucity of identifying information to make an appropriate link. However, with a prospectively collected file and thus, opportunities for collecting adequate identifiers, this error should be minimal. The second is the possibility that some exposed workers may migrate abroad. When those who migrate to the United States (and are still regarded as Canadian residents) die, a copy of their death certificate is automatically forwarded to Statistics Canada, so that the fact of death would be identified through record linkage. This, however, does not apply to those who migrate to other countries; yet the numbers are believed to be very small and not likely to introduce any appreciable error in the comparison of observed numbers of events with those expected.

The nature and purpose of epidemiological surveillance will vary depending upon whether a known or suspect carcinogen is involved.

1. Exposure to Known Carcinogens

Here, an individual is known to have been exposed to an established carcinogen. The object of surveillance in this instance is to provide protection of the individual at risk. This principle is already established for radiation workers for whom exposure records are maintained and, in general, detectors to monitor exposure are worn. If, as will often be the case, it proves impossible to prevent the occurrence of cancer, such monitoring enables the provision of compensation for disease if it occurs in spite of precautions taken. It is essential that research into appropriate prophylactics and secondary prevention continue in such exposed populations.

2. Exposure to Suspect Carcinogens

Epidemiologic surveillance for suspect carcinogens will have to be designed on a population level. The objective here is to ensure that it is possible to determine through epidemiologic methods that increased incidence of disease did or did not follow exposure to the substance for which evidence on its carcinogenicity has not been precisely obtained. In many instances, it will be sufficient to maintain records at the individual factory or plant level and not require them to be collected regionally or nationally. Exposure records should be maintained in as much detail as possible, in order to identify those individuals who have been placed at possible increased risk. A difficulty with this sort of assessment will be the nature of the comparison group, i.e. the controls. In many instances, a general population comparison group may be inappropriate, it being more appropriate to make comparisons with individuals working in similar occupations in the same or different plants who have not been exposed to the suspect carcinogen. There may also be problems of assessment of confounding factors such as, for a number of cancers, cigarette smoking, and, as far as possible, therefore, the individual records that have been maintained at the plant level should contain notation of cigarette smoking as well.

In general, as already indicated, these records will not be collected centrally. Although industry may object to the cost of maintaining them, it is common experience that this type of record, though sometimes incomplete in terms of personal identifiers or cigarette smoking exposure, can generally be retrieved from well-managed plants. In other words, the information required for this type of surveillance is already being collected, often in computerized form. All that is needed, therefore, is that an additional reason for its collection be acknowledged for those exposed to known and suspect carcinogens, and that the identity of those exposed and the type of exposure should be formally recorded and made accessible, as required, in the future.

Lessons

1. Screening for carcinogens by short-term and animal tests will help to reduce the risks, but will not eliminate all dangers from the workplace. Epidemiological surveillance and record linkage, now available on a national basis, should be utilized to detect risks in those exposed to known or suspect carcinogens.
2. In the case of exposure to known carcinogens, a monitoring system should be established to provide ongoing protection of the individual at risk (e.g. radiation workers). Exposure records should be maintained in order that compensation can be provided where cancer develops, despite precautions taken, and in order that new standards may be developed, if necessary.
3. Epidemiological surveillance of those exposed to suspect carcinogens can be designed to detect increased incidence of disease following exposure to a substance for which evidence on its carcinogenicity has not been precisely obtained.
4. The basic requirement for utilization of the existing surveillance systems is that full personal details, including Social Insurance Number or other unique personal identifier, be provided.

5. The continued existence of provincial cancer registries, such as the Ontario Cancer Registry, must be ensured in order that full cancer surveillance can be maintained.
6. Existing industrial practice, in well-managed plants, of maintaining exposure records should be encouraged and developed in order that complete and detailed records are kept of those exposed to known and suspect carcinogens, and are available for study and record linkage purposes.

References

1. Bradford Hill, A. The environment and disease: Association or causation? Proc. Roy. Soc. Med. 58:295-300, 1965.
2. Taken from: Cancer in Ontario 1980. The Ontario Cancer Treatment and Research Foundation.
3. Higginson, J. Proc. 8th Canadian Cancer Conference (1968) p.43.
4. Higginson, J. and Muir, C.S. Environmental carcinogens: Misconceptions and limitations to cancer control. J. of the Natl. Cancer Inst. 63:1291-1298 (1979).
5. Hammond, E.C., Selikoff, I.J. and Seidman, H. Asbestos exposure, cigarette smoking and death rates. Ann. NY Acad. Sci. Vol. 330, p.481 (1979).
6. Wynder, E.L. and Gori, G.B. Contribution of the environment to cancer incidence: An epidemiologic exercise. J. of the Natl. Cancer Inst. 58:825-832 (1977).
7. Quantification of occupational cancer. (Banbury Report: 9) Cold Spring Harbor Laboratory, 1981.
8. Fox, A.J. and Adelstein, A.M. Occupational mortality: Work or way of life? J. Epidemiol. Community Health 1978; 32:73-78.
9. Doll, R. and Peto, R. The Causes of Cancer: Quantitative estimates of avoidable risks of cancer in the United States today. J. of the Natl. Cancer Inst. Vol. 66: 1191-1308 (1981).
10. Correspondence with the Workmen's Compensation Board, April 8, 1982.
11. IARC Monographs on the evaluation of carcinogenic risk of chemicals to man. Supplement 2, 1980. Long-term and short-term screening assays for carcinogens: A critical appraisal.
12. Weisburger, J.H. and Williams, G.M. Carcinogen testing: Current problems and new approaches. Science, Vol. 214, p.401 (1981).
13. National Cancer Institute (USA) Guidelines for carcinogen bioassay in small rodents, 1976.
14. Advisory Memorandum on Policies and Principles for the use of Information in the Prevention of Occupational Accidents and Illnesses. Advisory Council on Occupational Health and Occupational Safety, Third Annual Report, 1980-81 p.168.

APPENDIX A
Case History — Ionizing Radiation

Radiation hazards have been under scrutiny for over 80 years. This very extensive experience with a physical carcinogenic agent has led to the development of concepts which are applicable to other carcinogens. The most important of these is the non-threshold concept, which indicates that some degree of risk is associated with any exposure to ionizing radiation. This concept leads to an emphasis on estimation of risk, rather than on determination of a 'threshold dose'.

Awareness of the long-term effects of radiation exposure led to the development of an approach to radiation protection designed to prevent industrial injury in advance, instead of waiting to apply a remedy if overt harm developed. This system of dose limitation has been based on the concept of 'maximum permissible' radiation exposure.[1] The non-threshold concept implies that the 'maximum permissible' dose cannot be regarded as a safe (no effect) dose, but only as a basis for administrative control of radiation exposure. A regulatory limit of this type involves two very different kinds of activity. One is the quantitative estimation of risk. The other involves making judgements about the acceptability of risk. The latter must include a consideration of tradeoffs between benefits and hazards. Only the first of these can be regarded, at present, as an empirical, scientific activity.[1,2,3]

Brief Historical Perspective

Ionizing radiation (including X- and gamma-rays, electrons, alpha particles and neutrons, but not radio waves, microwaves, infrared, visible or ultraviolet radiation) is often looked upon as an agent which has only recently appeared in the environment. This is not the case; there are several natural sources of 'background' radiation exposure, including terrestrial radiation from naturally-occurring radioactive elements in soil and rock, cosmic radiation, and radiation from radioactive elements in our bodies. However, occupational exposure to ionizing radiation only became of significance following the discovery of X-rays in 1895 and of radioactivity in 1896. These discoveries led quickly to a variety of applications; for example, the remarkable penetrating power of X-rays had already been exploited by Roentgen in late 1895, to make an X-ray photograph of his wife's hand. The fact that ionizing radiation can damage living tissue also became apparent very quickly; hair loss following X-ray photography was reported four months after Roentgen's announcement.[4]

The best documented early group of radiation injuries are those of the radium dial painters in New Jersey.[5] Luminous paint production and its applications were introduced into North America about 1913; signs of radiation injury were recognized about 1923 and the first published reports appeared in 1925. The luminous watch-dial painters had inhaled or swallowed radium which, being chemically similar to calcium, was incorporated into bone. These workers were thus chronically exposed to radiation. At high levels of exposure (well above 100 rads per year), acute destruction of bone and bone marrow resulted in death within a few years. At lower exposure levels, the bone lesions were less acute; the affected workers lived longer, some long enough to develop bone cancers. Those dial painters who received an estimated average total skeletal dose of approximately 10^4 rads (100 Gy) showed the highest incidence of tumours; more than 40 per cent of those individuals developed bone sarcomas.[6] There were very few cases of leukemia, although there is good evidence (especially from the survivors of the atomic bomb explosions at Hiroshima and Nagasaki) that irradiation of the bone marrow can lead to an increased incidence of leukemia.[2]

The experience of early workers in radiation also revealed that repeated doses of radiation that are too small to produce any immediate reaction may eventually have an effect. For example, the hands of many pioneer radiologists were exposed repeatedly to radiation of low penetrating power from low-voltage X-ray machines, because of the practise of checking X-ray tube operation by using the hand as the test object. After a time, they gradually developed dry cracked skin, brittle fingernails and poorly healing ulcers that, years later, became cancerous.[7]

Sources of Radiation

The major sources of ionizing radiation to which the general population is exposed are natural background radiation, and medical applications of radiation (Table 1). For a given person, the dose from natural background varies with altitude and geographic location, as well as living habits. Occupational exposures may exceed background by severalfold.[2]

Table 1

Annual Dose Rates From Some Important Sources of Radiation Exposure in the U.S.

Source	*No. Exposed*	*Average dose rate to exposed group (m rem/yr.)*
Natural background:		
Cosmic radiation	220×10^6	28
Terrestrial radiation	220×10^6	26
Internal sources	220×10^6	24 (BM)*
Medical X-rays:		
Medical diagnosis	105×10^6/yr	103 (BM)
Medical personnel	195,000	300 – 350
Dental diagnosis	105×10^6/yr	3 (BM)
Dental personnel	171,000	50 – 125
Radiopharmaceuticals:		
Medical diagnosis	10×10^6/yr	300 (BM)
Medical personnel	100,000	260 – 350
Nuclear Industry:		
Nuclear power plants	67,000	400
Industrial radiography	11,250	320
Research Activities:		
X-ray diffraction units	10,000 – 20,000	?
Airlines:		
Crew members	40,000	160

*BM = dose to bone marrow

Taken from: Reference 2, pp. 84–87 (This report, familiarly known as BEIR III, contains a wealth of detailed information).

Radiation Dose Measurement

Extremely sensitive methods are available for the measurement of radiation dose. Major difficulties in the measurement of dose usually arise only when radiation doses must be estimated after the fact. For example, for the Japanese atomic bomb survivors, great efforts have been made to determine the dose-distance relationships of the bombs, to locate the site of exposure of each person in the city at the time of the bombing, and to determine the degree of shielding by buildings or terrain that may have reduced radiation exposure.

Units of radiation are the rad (0.01 joule/kg of absorbed dose) and the rem (absorbed dose multiplied by a correction factor to allow for differences between radiations in their biological effects); these older units are now being replaced by two new units, the gray (1 Gy = 100 rads = 1 J/kg) and the sievert (1 Sv = 100 rems). Very low levels of exposure are usually expressed in millirems per year (1 rem = 1000 mrem).

Radiation Biology

The relationship of radiation biology to radiation carcinogenesis is similar to that of pharmocology to chemical carcinogenesis. However, ionizing radiation is unique, in that the energy it deposits in biological material is distributed in discrete packets, essentially at random, along the tracks of charged particles set in motion in the material as a consequence of transfer of energy from the radiation to the material. Because of the penetrating power of many ionizing radiations, and the random nature of the deposition of energy, no component of the irradiated material is spared.

Theoretical considerations, and cellular and animal data, suggest a model for the dependence of biological effects on dose at relatively low doses, well below 100 rads, where the cell-killing effects of ionizing radiation are negligible. The model is a linear quadratic dose response curve[2,8]:

$$E = a_0 + a_1D + a_2D^2$$

where D is the radiation dose, E is the incidence of effects (e.g. cancer) at dose D, a_0 is the control, or spontaneous rate of the effect under study, and a_1 and a_2 are positive-valued parameters that depend on a number of factors related to the nature of the ionizing radiation and of the biological effect involved. This functional form can be viewed as a basically linear function ($a_0 + a_1D$) with a modification that allows the curve to express upward (positive) curvature (a_2D^2).

The essential features of the linear-quadratic model are[3]:

1. Ionizing radiation produces elementary lesions, in numbers proportional to the absorbed dose, within a small sensitive site in the biological material.
2. If two lesions occur close enough together in space, they can interact to produce a biological effect. The probability that two lesions will occur in the same critical volume is determined by the dose.

3. For sparsely-ionizing radiation (such as high energy electrons set in motion by X- or gamma rays), each of these interacting lesions will be produced independently of each other (that is, by independent charged particles), thus producing a dose-response curve proportional to dose squared.
4. For more densely-ionizing radiation (such as alpha radiation, the recoil protons produced by neutrons, or low-energy electrons), both of the interacting sublesions can be produced by one particle and the dose-response curve will be linear (directly proportional to dose).
5. Some forms of radiation damage in biological material are repairable; thus two lesions that do not occur close enough together in time may not interact to produce a biological effect. The probability that two lesions occur within a given time interval is determined by the dose-rate.

Thus, for very low doses and low dose rates, for either sparsely or densely-ionizing radiations, the dose response curve should approach linearity.

The nature of the dose-response curve is of great importance in risk estimation, since extrapolation from high dose levels to low levels is required. If the linear-quadratic model is correct, it is likely that effects at low dose levels, at least for sparsely-ionizing radiation, will be overestimated on the basis of a linear extrapolation of data obtained at high doses and dose rates.

The validity of the linear-quadratic model, relative to a more conservative linear model, as a basis for risk estimation remains controversial; for a thorough discussion of the issue, see the BEIR III report.[2]

Types of Cancer Induced

Cancers induced by ionizing radiation are indistinguishable from those occurring naturally; hence, their existence can be inferred only on the basis of a statistical excess above natural incidence. This means that the cancer of any given person cannot be attributed with certainty to radiation, as opposed to some other cause.

Cancer may be induced by ionizing radiation in nearly all the tissues of the human body, although tissues and organs vary considerably in their sensitivity. Leukemia stands out because of the relative ease of its induction by radiation, and its short latent period (2-4 yrs.). When the total risk of radiation-induced cancers is considered, it is clear that the risk of other cancers exceeds that of leukemia.

The major radiation-induced cancers are summarized in Table 2, taken from the BEIR III report.[2]

Table 2

Major Radiation-induced Cancers

Site or type	*Spontaneous incidence*	*Relative sensitivity to radiation induction*
Female breast	Very high	High
Thyroid	Low	Very high (esp. for females)
Lung (bronchus)	Very high	Moderate
Leukemia	Moderate	Very high
Alimentary tract	High	Moderate to low

Latent Period

The time elapsing between irradiation and the appearance of a detectable neoplasm is characteristically long; that is, years or even decades.[2] The excess risk of leukemia appears within a few years after radiation exposure and largely disappears within 30 years after exposure. For other cancers, latent periods appear to be longer; they seldom appear before 10 years after radiation exposure and may continue to appear for 30 years or more after radiation exposure. Because of the very long latent periods which may separate exposure to radiation and the development of detectable effects in man, the true health risk of radiation exposure can be assessed only with extremely long followup (30 years or more) of the populations under study. It is usually necessary to make some assumptions about the way in which further cases are likely to appear in later years. Examples of two models for projecting the effect of radiation exposure at a particular dose level are the 'absolute-risk' model, and the 'relative-risk' model. In the former, absolute risk is defined as the number of excess cancer cases per unit of population per unit of time and per unit of radiation dose, and, although it may depend on age at exposure, it is assumed not to depend otherwise on age at the time of observation for assessment of risk. In the second model, excess cancer risk for the interval after the latent period is expressed as a multiple of the natural age-specific cancer risk for that population. The chief difference between the two models is that the latter involves the assumption that the absolute risk of radiation-induced cancer varies by age at observation and is proportional to the risk of spontaneous development of cancer in the population. For either model, the total risk to an irradiated population for its entire life span can only be estimated by making an assumption about how long the risk will remain increased. Reasonable estimates can be made for leukemia and for bone cancer arising from radium-224 exposure, but for virtually all other radiogenic cancers, excess risk has not decreased 30 years or more after exposure, and final risk estimates cannot be made.

Effect of Age

The most important factor influencing the risk of spontaneous cancer is age. The available data show that age at exposure to ionizing radiation has an important influence on its carcinogenic effect. If the relative-risk model (see above) applies, then the age of the exposed groups at the time of observation also becomes important. However, the influence of age is not uniform in human carcinogenesis.[2] For example, the clearest evidence of a very high risk in those irradiated in the first years of life is provided by the age-specific data for leukemia induction for atomic-bomb survivors. The excess risk of breast cancer appears to be highest for women exposed in the second decade of life, when major hormonal changes are taking place. For lung cancer, there is little evidence of increased risk before the age of 35, regardless of the age at exposure, but the risk at later ages increases steeply, as does the risk in the general population. For the major solid tumours, whatever the age differential in susceptibility, a differential in the length of the minimal latent period seems quite well established; persons irradiated at higher ages in general develop cancer sooner than those irradiated at lower ages. An association between prenatal exposure to ionizing radiation and an increased risk of developing malignancy during childhood has also been established, but there remains some question as to the extent to which this represents a causal relationship.[2]

Other Variables

Various host or environmental factors may interact with radiation to affect cancer incidence in different tissues. A few principles are now evident.[2] For example, sensitivity to cancer induction is not proportional to the rate of division of stem cells; if it were, the small intestine should be as sensitive as the bone marrow, and it is not. Nor is sensitivity to radiation necessarily related to the influence of hormones. The female breast and the thyroid are quite sensitive to radiation, but the uterus and prostate are not.

Some groups in the general population appear to be at increased risk of induction of cancer by radiation. For example, cigarette smoking appears to lead to greater excess risk of lung cancer from radiation exposure, when smokers and non-smokers are compared. Smoking appears to shorten the latent period, but more information is needed to settle the question whether exposure to radiation simply adds to the effect of cigarette-smoking, or whether the effects are greater than additive when both are present.

There is increasing recognition that there are human genotypes that confer both increased cancer risk and abnormal sensitivity to carcinogenic agents, including ionizing radiation. To the extent that substantial population subsets can be identified in the future as being at particularly greater risk of radiation carcinogenesis, their risk merits separate consideration. However, current evidence would seem to be against large differences in sensitivity to ionizing radiation within the population.[6]

Risk Estimation

A clear-cut increase in cancer incidence and mortality with increasing radiation dose has been demonstrated for many types of cancer in human populations, as well as in laboratory animals. However, the quantitative estimation of the carcinogenic risk of radiation is subject to numerous uncertainties. The greatest of these concerns is the shape of the dose-response curve, especially at low doses. Estimates of risk at low doses depend more on what is assumed about the mathematical form of the dose-response relationship than on the data themselves.[8] The uncertainties involved in the estimation of carcinogenic risk are such that it is not clear whether or not dose rates of gamma or X-rays of about 100 mrads/yr. (i.e., equivalent to natural background radiation) or less are detrimental to man. Any carcinogenic effects at these dose rates would be masked by environmental or other factors that produce the same types of health effects as does ionizing radiation. Indeed, in studies of either animal or human populations, the shape of a dose-response relationship may be practically impossible to ascertain statistically. This is because the sample sizes required to estimate or test a small absolute cancer excess are extremely large, e.g. of the order of 100,000 exposed and 100,000 control subjects are required to test the cancer excess adequately for a dose of 10 rads.[2] Because of this uncertainty, there has been no general agreement over the choice of a mathematical model; the linear and quadratic models can lead to widely diverging estimates at low dose levels, with the linear-quadratic model yielding intermediate values. As discussed above, the linear model provides a conservative approach; although it may overestimate risks at very low dose levels, it is unlikely to underestimate them.[9]

Other uncertainties involved in risk estimation pertain to the length of the latent period, the biological effectiveness of fast neutrons and alpha radiation relative to gamma and X-radiation, the period during which the radiation risk is expressed, the model used in projecting risk beyond the period of observation, the effect of dose rates or dose fractionation, the influence of differences in the natural incidence of specific forms of cancer, and others.

The chief sources of human data are the populations exposed to whole-body irradiation at Hiroshima and Nagasaki, patients with ankylosing spondylitis and other patients who were exposed to partial-body radiation therapeutically, and various occupationally-exposed populations, such as uranium miners and radium-dial painters. Most epidemiologic data do not systematically cover the range of low to moderate doses for which the Japanese data appear to be fairly strong. Analysis in terms of dose-response therefore relies rather heavily on the Japanese atomic-bomb survivor data.

There are some problems in the use of epidemiological studies as the principal source of information about the carcinogenic effects of ionizing radiation on human populations.[2] The main problems are:

1. Generally, the group has been exposed to radiation because of some particular characteristic, and thus may not be representative of the population as a whole.
2. Most such studies are retrospective. That is, exposure to radiation occurred in the past, and the exact dose delivered to individuals or to a group may not be known.
3. Very long latent periods may separate exposure to radiation and the development of detectable effects in man. This is a problem especially if the latent period is influenced by demographic variables such as age at exposure.

Although risk estimation at low dose levels involves the various sources of uncertainty outlined above, some numerical risk estimates can be given. For doses of sparsely-ionizing radiation of the order of 50 rads, the absolute lifetime risk of mortality from cancer is about 10^{-4} per person per rad, for young adults, averaged for both sexes.[6] If tumour incidence, rather than mortality, is used, the estimates are somewhat higher. For continuous lifetime exposure to 1 rad per year, on the basis of the linear-quadratic dose response model, the increased risk expressed as per cent of the normal incidence of cancer in males is about two per cent – six per cent, depending on the projection model used (absolute-risk or relative-risk).[2,10] Risk for females is substantially higher than that for males, due primarily to the relative importance of radiation-induced thyroid and breast cancer.[2]

Risk Assessment

The elements of risk assessment are three-fold: risk identification, risk estimation, and risk evaluation.[11] Identification of ionizing radiations as carcinogenic agents is well-established; all of the criteria of causation described by Bradford Hill[12] are satisfied. Quantitative risk estimation is possible, as is outlined in the previous section. It is the third element of risk assessment, risk evaluation, that poses major problems in terms of quantitative analysis.

If the concept of a non-threshold dose-response function is accepted, it follows that any risk associated with man-made radiation must be compensated for by an appropriate benefit. There is no general agreement about how the quantitative comparison of risks and benefits should be made. Early approaches to the regulation of radiation exposure were based, at least partly, on the concept of 'absence of serious harm'.[6] Over the past 25 years, this concept has been replaced by the concept of 'acceptable level of risk'. One quantitative approach to the definition of an acceptable level of risk is to utilize the concept of 'comparative risk', such that risks from sources of hazard other than radiation play a role in determining acceptability of risk.[6] However, perceptions of risk must also be included in judgements about the acceptability of estimates of comparative risk.[6] Empirical work has shown that a variety of factors can strongly influence attitudes toward risk.[13,14] For example, people usually consider voluntary risks to be much more acceptable than involuntary ones. They tend to trust familiar, concrete experiences more than abstract statistics, and to overestimate the magnitude of risk associated with dramatic and sensational causes of death relative to the risk associated with potentially lethal events that are also common in nonfatal forms.[15] Thus, judgements of the acceptability of comparative risk (such as the risks associated with exposure to ionizing radiation relative to other potentially hazardous activities) are open to a number of biases. There is no general agreement about how such biases might be taken into account in policy-making.

Other approaches to the regulation of radiation exposure have also been considered; again, no consensus has emerged. An example is the 'de minimus' concept, that a specified increase in hazard level might be considered acceptable in order to achieve compensatory benefit, provided that the added hazard level remains small in comparison with the variation that already exists. For radiation exposure, the de minimus level might be defined as some specified proportion of the standard deviation in population exposure to natural background radiation.[3] Natural radiation levels are relatively well-known; cosmic radiation levels vary with altitude, by about two-fold from sea level to 1500 meters (5000 feet). Terrestrial radiation varies considerably also; in some heavily-populated parts of Yangjiang County, Guangdong Province, China, the terrestrial radiation level is about three times that in neighboring areas.[16] In some populated locations, such as the area of monazite sand in Kerala, India, the terrestrial radiation levels are much higher.[17]

For any arbitrarily chosen level of risk for which the degree of harm is presumed to be 'acceptable' relative to the expected benefits, there is the concern that those who undertake activities in order to receive benefits are not always those who must take the risks. An approach which pays some attention to this aspect of risk evaluation is the ALARA principle: as low as reasonably achievable in all areas of exposure to ionizing radiations, economic and social factors being taken into account.[18] Two factors influence practical applications of this principle[11]: even very low exposures involve risks that require compensating benefits, and the cost of control measures needs to be offset by benefits of reduced risk. It cannot be assumed that conservative estimates of risk do not involve any concomitant increase in costs. For example, penetrating high energy gamma radiation is attenuated by shielding materials such as lead or concrete according to a negative exponential rather than a linear relationship.[19] This means that the thickness (and cost) for the shielding materials must increase by approximately two-fold for each two-fold reduction in the dose-rate of the emergent radiation, and an infinite thickness is required to achieve a zero dose-rate.

Approaches to the analysis of risks associated with ionizing radiation continue to evolve. Recent revisions of dose estimates at Hiroshima and Nagasaki[20] may have some impact on risk estimation. Risk assessment remains a controversial topic, and is being studied intensively by a series of national[2] and international[21] committees. Present policy in Canada for penetrating high energy X- or gamma radiation[22] is based on what may be regarded as a compromise approach involving the ALARA principle, the 'de minimus' concept, and the concept of a 'permissible' level of radiation exposure. Reasons must now be given why any exposure of the general public to man-made radiation exceeding 5 millirem per year should be permitted. This low level of exposure (corresponding to about five per cent of the background level from natural sources) has become, in effect, the current guideline concerning exposure to penetrating high energy ionizing radiation for a member of the general public. Departures from this level of exposure are based on the ALARA principle, in that they must be justified as being as low as reasonably achievable, economic and social factors being taken into account. It should be emphasized that this policy for penetrating high energy radiation is *not* based on the concept of 'comparative risk'.[6] The risks associated with ionizing radiation are, at present, perceived to be much less acceptable than those associated with a variety of other potentially hazardous activities,[23] even for equivalent levels of estimated 'objective' risk.

References

1. Science Council of Canada. Report No. 28. Policies and Poisons. The Containment of Long-Term Hazards to Human Health in the Environment and the Workplace. Minister of Supply and Services, Canada, 1977.
2. Committee on the Biological Effects of Ionizing Radiations. The Effects on Populations of Exposure to Low Levels of Ionizing Radiation. National Academy of Sciences, Washington, 1980.
3. H.L. Friedell. Radiation Protection-Concepts and Trade Offs. National Council on Radiation Protection and Measurements, Washington, 1979.
4. J. Daniel. The X-rays. Science *3*: 562–563, 1896.
5. H.S. Martland. The occurrence of malignancy in radioactive persons. Am. J. Cancer *15*: 2435–2516, 1931.
6. W.K. Sinclair. Effects of low-level radiation and comparative risk. Radiology *138*: 1–9, 1981.
7. J. Furth and E. Lorenz. *In*: Radiation Biology, vol. 1 (A. Hollaender, ed.) McGraw-Hill, New York, 1954, pp. 1145–1201.
8. C.E. Land. Estimating cancer risk from low doses of ionizing radiation. Science *209*: 1197–1203, 1980.
9. B.L. Cohen. The cancer risk from low-level radiation. Health Physics *39*: 659–678, 1980.
10. J.I. Fabrikant. The BEIR-III Controversy. Radiat. Res. 84: 361–368, 1980.
11. W.S. Rowe. An Anatomy of Risk. Wiley, New York, 1977.
12. A. Bradford Hill. The environment and disease: Association or causation? Proc. Roy. Soc. Med. *58*: 295–300, 1965.
13. P. Slovic, B. Fischhoff and S. Lichtenstein. In: Cognition and Social Behavior (J.S. Carroll and J.W. Payne, eds.) Erlbaum, Hillsdale, N.J. 1976, pp. 165–184.
14. A. Tversky and D. Kahneman. The framing of decisions and the psychology of choice. Science *211*: 453–458, 1981.
15. Editorial. The risks of assessing risks. Brit. Med. J. *281*: 1374, 1980.
16. High Background Radiation Research Group, China. Health survey in high background radiation areas in China. Science *209*: 877–880, 1980.
17. A.R. Gopal-Ayengar, K. Sundaram, K.D. Mistry, C.M. Sunta, K.S.V. Nambi, S.P. Kathuria, A.S. Basu, and M. David. Evaluation of the long-term effects of high background radiation on selected population groups on the Kerala coast. Proc. 4th Int. Conf. Peaceful uses of Atomic Energy *11*: 31–51, 1972.
18. K.Z. Morgan. Cancer and low level ionizing radiation. Bull. At. Sci. *34*: 30–41, 1978.
19. National Council on Radiation Protection and Measurements. Structural Shielding Design and Evaluation for Medical use of X-Rays and Gamma Rays of Energies up to 10 MeV. National Council on Radiation Protection and Measurements, Washington, 1976.
20. W.E. Loewe, and E. Mendelsohn. Revised dose estimates at Hiroshima and Nagasaki. Health Physics *41*: 663–666, 1981.

21. International Commission on Radiological Protection. Recommendations of the International Commission on Radiological Protection. Publication 26. Pergamon Press, Oxford, 1977.
22. Atomic Energy Control Board. Guidelines for applicants for licences of medical accelerators. Document AG-5. Atomic Energy Control Board, Ottawa, 1979.
23. International Commission on Radiological Protection. Problems involved in developing an index of harm. Publication 27. Pergamon Press, Oxford, 1977.

APPENDIX B
Case History — Vinyl Chloride

One Model for a Human Chemical Carcinogen

The model of vinyl chloride induced chronic disease, in particular liver cancer, is both interesting and informative for several reasons:[1]

1) the relatively short and well-defined time period for its use,
2) the characteristic end points for health — chronic bone and soft tissue changes (acro-osteolysis) and angiosarcoma of the liver,
3) a readily identifiable exposure pattern,
4) a great interest in the problem by many segments of the population,
5) the ready availability of animal models, and
6) a fairly easy and acceptable way to handle the problem in the workplace.

A. Brief Historical Perspective

Vinyl chloride (VC) is one of the major intermediates in the commercial production of one of the most important plastics, polyvinyl chloride (PVC). VC is a gas at ordinary room temperature and pressure but is easily compressed to form a liquid. It is readily polymerized to form PVCs.

The world productive capacity has increased very significantly from 1950 to the 1970s. For example, the capacity increased in Western Europe by about 75 fold from 1950 to 1972 and in the USA by about one-and-a-half fold from 1972 to 1975.

VC was shown to be toxic to animals in 1960[2] and found to induce vascular disease with bone destruction (acro-osteolysis) in 1963 in Romania.[3] It was found to induce cancer in several sites in 1970,[4] and angiosarcoma of the liver in humans in 1974.[5] The human pathological picture was largely reproduced in experimental animals in respect to chronic liver disease including liver cancer.[6] Thus, within less than a 15-year period, the major acute and chronic disease patterns induced by exposure to VC were described.

The total work population in the USA concerned in some way with VC, past and present, has been estimated at about 20,000.[1] However, there is some evidence that a much larger population may have some hazardous exposure because of:

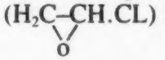
1) significant loss of VC to the atmosphere at selected sites with subsequent atmospheric transport,
2) proximity to VC and PVC production areas,
3) consumption of food products containing leakable amounts of unreacted VC from PVC-packaged materials, and
4) ingestion of water containing unreacted VC leaked from PVC pipes.[7]

How great the risk is in such groups is not known.

B. Characteristics

a) Metabolic Activation and Reaction With Cellular Constituents

There is now clear-cut evidence that VC per se is not the likely carcinogen but rather a chemically reactive derivative generated enzymatically in the liver (and possibly elsewhere).[8] This would place VC in with the majority of chemical carcinogens that require metabolic conversion to active compounds that in turn can react with many components in the tissues including DNA. In several test systems *in vitro*, VC has been found to be mutagenic, especially in the presence of purified liver microsomes capable of carrying out some type of metabolic conversion. The exact chemical form (or forms) that is the 'ultimate carcinogen' is not known. Chloroethylene oxide, the epoxide of VC, $(H_2C\underset{\backslash\,O\,/}{-}CH.CL)$ is considered to be a likely candidate.



Thus, in respect to metabolic activation, mutagenic activity after activation and interactions with cellular constituents, VC is quite a typical chemical carcinogen.

b) Exposure Pattern

It is already evident that exposure to VC need not be continuous up until clinical cancer appears.[9] In three of the first cases reported, initial exposure (as a 'helper' cleaning out the interiors of polymerization vats) of only an average of 5.3 months resulted in liver cancer 22 years later, while in four cases, the exposure averaged 34.5 months and cancer appeared 14.5 years later.

The available evidence indicates that even removal of the person from further exposure to VC may nevertheless not prevent cancer appearance years later. Thus, certain tissue changes appear to be fairly irreversible. In the first 13 patients in the USA, the total exposure in VC work varied from 13 to 29 years. This, coupled with the current understanding of the pathology and pathogenesis,[10] makes it almost certain that VC-induced angiosarcoma, like most other malignant neoplasms of many sites, develops as a multistep process with the probable occurrence of non-neoplastic or non-cancerous changes some considerable time before cancer appears. This process could well take from 15 to 25 years or more, depending upon the intensity and duration of exposure and other unknown factors.

c) Initiation — Promotion

The available data on VC carcinogenesis in humans, although far from extensive, nevertheless are consistent with the data from other human exposures to other carcinogens and from extensive animal experience in indicating that the first step or steps in the carcinogenic process might well be irreversible. This would fit well with the concept that initiation of the carcinogenic process begins as a few steps generating some change that can persist for a long time. This is most easily interpreted as a mutation-like event, although other possible mechanisms of inducing an irreversible change in the behaviour of a cell have not been ruled out.

The identity of any possible promoting agents, other than the carcinogen itself is quite unknown.

d) Organ and Cell Specificity

The appearance of a rare form of cancer of the liver, angiosarcoma, with exposure to VC has no readily apparent explanation. This form of liver cancer is seen with several different carcinogens in experimental animals, in addition to VC. Dimethylnitrosamine, dimethylhydrazine and urethane are among the carcinogens that induce this form of liver cancer in animals. In humans, thorotrast, the particulate form of the radioactive compound thorium dioxide, also induces a similar form of liver cancer after many years.

One possible explanation was suggested recently.[11] Dimethylhydrazine (DMH) was shown to react with both liver parenchymal cells and vascular endothelium but the repair of the damaged DNA was found to be much slower in the latter cells. DMH under some conditions induces mostly angiosarcoma.

Another possible explanation may relate to the general effects of VC on blood vessels including both fingers and liver. The initial damage to cells by VC could be relatively non-specific in the liver. However, the promoting action of VC could be much more vigorous on the blood vessels since these seem to be damaged generally by VC. Thus, the specificity could reside in the post-initiation events rather than in those related to initiation.

e) Threshold and Dose Response

The question of threshold may be critical to our eventual control of cancer. Are there safe levels of exposure?

There are some data indicating that there is a rough correlation between degree of exposure to VC and the duration of the period taken to develop clinically evident cancer. However, the data are not many and throw no light upon the question of the existence of a threshold for carcinogenicity.

C. Control

This is an excellent example of a situation where vigorous action on the part of industry and the authorities has led to rapid and radical change in the workplace. Whereas, a few years ago, discussions were concerned with whether 50 ppm is a feasible level to strive for, the vigorous insistence by some authorities on a 'zero' level has stimulated many industries to introduce automation to the point where 0.5 ppm is readily attainable in the workplace in at least some countries (e.g. Sweden).

Thus, the attitudes and the technology have rapidly merged to make the workplace in PVC production a much safer environment than was thought possible five years ago. In this respect, the VC model is particularly attractive and deserves widespread acknowledgment.

References

1. Toxicity of vinyl chloride- polyvinyl cloride. Ann. N.Y. Acad. Sci., Vol. 246, 1975.
   Occupational carcinogenesis. Ann. N.Y. Acad. Sci., Vol. 271, 1976 pp 49, 176.
   Public control of environmental health hazards, Vol. 329, pp 183–209, 1979.
2. Mastromatteo, E., Fisher, A.M., Christie, H. and Danziger, H. Am. Ind. Hyg. Assoc. J., *5*: 395, 1960.
3. Suciu, I., Diegman, I. and Valaski, M. Med. Interna., *15*: 967, 1963.
4. Viola, P.L. Med. Lavoro *61*: 174, 1970.
5. Creech, J.L. and Johnson, M.N. J. Occup. Med., *16*: 150, 1974.
6. Maltoni, C. and Lefemine, G. Environm. Res., *7*: 387, 1974.
7. Fishbein, L. Adv. Modern Toxicol., *5*: 257, 1978.
8. Miller, E.C. Cancer Res., *38*: 1479, 1978.
9. Heath, C.W., Falk, H. and Creech, J.L. Ann. N.Y. Acad. Sci., *246*: 231, 1975.
10. Thomas, L.B. and Popper, H. Ann. N.Y. Acad. Sci., *246*: 268, 1975.
11. Lewis, J.W. and Swenberg, J.A. Nature, *288*: 185, 1980.

APPENDIX C
Case History — Smoking

a) Lung Cancer

In Canada, lung cancer is the most important cancer in men and is rapidly approaching this position in women.[1,2] Internationally, the highest incidence rates in males are reported from Liverpool in the United Kingdom, the lowest rate from Ibadan in Nigeria.[3] It is notable that a moderately low rate is reported from Utah in the United States where a high proportion of the population are Mormons who do not smoke. In females the highest rate is in the Maoris of New Zealand with oriental populations from a number of areas (Bay area of the U.S., Hawaii and Singapore) showing high rates, as well as white females in the Bay area and Hawaii. Canadian registries occupy an intermediate position in both sexes.

A useful way of presenting rates for comparative purposes is to cumulate incidence. If you cumulate rates to age 75 you achieve an approximation to a lifetime incidence of the disease in question, excluding other competing causes of death. In Canada, currently the cumulative incidence for lung cancer to age 75 approximates to six per cent for males and is just over one per cent for females. There are substantial variations in these rates internationally and in the changes that have occurred (Table 1). For example, in Liverpool, cumulative incidence has shown a 14 per cent increase to 11.6 per cent, in Connecticut it increased 24 per cent to 6.9 per cent, in Saskatchewan 64 per cent to 4.6 per cent, and in the Singapore Chinese over 400 per cent to 7.6 per cent, though the earlier figures were based on rates in 1950–61. In females similar, if not larger, changes have occurred. Thus, in Saskatchewan there has been over a 100 per cent increase to 0.8 per cent.

Many years ago the changes that were occurring in mortality from lung cancer were interpreted as showing the influence of an environmental factor.[4] Changes are still continuing as is shown with the continued upward trend in mortality from lung cancer in Canada[1] though the rate of increase is less now in males than in females.[2] The marked international variation confirms the importance of environmental factors as do the changes that have occurred in the rates of disease in groups of migrants. Those who migrate from Britain to Canada, Australia and South Africa tend to end up with rates intermediate between those they might have been expected to have encountered if they had remained in Britain and those that prevailed in the host country, even when account is taken of differences in smoking intensity.[5-7] The older they were when they migrated, the nearer their rates corresponded to those of Britain. This would seem to suggest that the British were carrying with them a factor related to background exposure to possible causative factors when young, such as virus infections of the respiratory tract or maybe air pollution. Such increased risk seems unlikely to be of genetic origin, even though some studies have suggested familial associations of lung cancer.[8] In some countries there has been an indication, particularly in males, of a down turn in mortality from lung cancer at certain ages.[9,10] In Canada, we are just beginning to see such an effect in males between the ages of 40 and 49 though with a suggestion of a reduction in the rate of increase in lung cancer at all ages, except possibly those older than 70.[2] In females there is, however, no indication of any slow down in the rates of increase of lung cancer at any age.

In view of the fact that the increases that were seen in mortality in every country appeared to follow the increase in tobacco usage, particularly cigarette consumption, after an appropriate latent interval, specific investigations of tobacco use and lung cancer were performed.[11,12] Initially conducted by comparing the tobacco usage experience in cases with lung cancer and suitable controls (the case-control approach), a number of different cohort (longitudinal) studies were performed in which groups had their tobacco experience identified, and their subsequent incidence and mortality from lung cancer, other cancers and other diseases monitored.[13,14] The long-term study of British doctors encompasses a 20-year follow-up period of an occupational group in which the effect of tobacco consumption could be efficiently determined without confounding from other occupational causes.[15] The study confirmed the increased risk of death from lung cancer with any tobacco use but most specifically usage of cigarettes and with a strong dose-response relationship between different cigarette consumption categories (Table 2). The very strong dose-response relationship and the high relative risks at high consumption levels point strongly to a causal association. The study also provided additional confirmatory evidence of a causal association by documenting reduced risk following cessation of cigarette smoking (Table 3). When expressed as a ratio of rates compared to non-smokers, continuing cigarette smokers had a ratio of 15.8:1, ex-cigarette smokers one of 2:1 after 15 years, or as 11 per cent of the risk in continuing cigarette smokers. However, a number of cautions are necessary in interpreting these data. First, it must be borne in mind that the comparisons are with those who continue to smoke or do not smoke. As continuing smokers age they increase their risk. Those who stop smoking appear to have acquired a certain degree of risk at the time they stop and this degree of risk persists, though in comparison with continuing smokers, it becomes less. In other words, cigarette consumption for a period results in cumulating a certain order of risk which then persists at that level even if exposure then ceases. The second caution relates to the fact that those who give up cigarette smoking are a self-selected group. An intervention study conducted among British civil servants has so far suggested no effect on overall mortality in a group where a majority ceased smoking compared to a group in which a minority ceased smoking.[16] Indeed, a recent analysis claims that, although mortality has fallen substantially from lung cancer and heart disease in physicians in Britain who have ceased smoking, this may have been partially offset by increases in mortality from other causes related to stress.[17]

One factor which might partially explain a deceleration in the increase in lung cancer mortality and incidence in various countries, is the shift that has occurred almost universally, except possibly in developing countries, to filter cigarettes burning tobacco with lower tar production.[10] As those who are currently dying from lung cancer are largely those who commenced smoking with non-filter cigarettes many years ago, it is difficult to dissect fully the effects of the earlier consumption from the more recent, possibly less hazardous consumption. In addition, there is evidence that those who shift to filter and lower tar brands tend to increase their consumption to compensate for the decreased nicotine[18,19] so that although comparisons have been made within cigarette smoking categories, the 20 or more filter cigarette smoker may have been a less than 20 non-filter cigarette smoker. Bearing these caveats in mind, however, in an American Health Foundation study the relative risk for non-filter smokers compared to long-term filter smokers was, after adjusting for various factors, estimated to be 1.3 for males and 1.4 for females.[20]

Lung cancer in women has not been subjected to the same intensity of study as for men. However, recently a follow-up of female British doctors has suggested that the relationship between smoking risk and lung cancer is similar to that of men at similar dose levels of cigarette consumption.[21] Marshall and his colleagues have also shown that women have similar smoking habits as men once they reach the 'addictive' stage of 20 or more cigarettes daily.[22] It seems likely, therefore, that the lower lung cancer rate in women is only a reflection of lower smoking levels overall, not a difference in biological susceptibility to the carcinogens in tobacco.

Currently in Canada, it would seem that cigarette smoking accounts for approximately 80 percent of the lung cancer in males and nearly 60 per cent in females.[2] This fraction, the attributable risk, is increasing in females though remaining approximately stable in males. It is important when considering such figures, however, to bear in mind that the attributable risk when a number of different factors have been included, can easily amount to more than 100 per cent. However, the concept implies that if you are able to remove a factor from the environment, then theoretically that amount of cancer currently occurring could be prevented.

A large number of different occupational factors have now been identified as associated with lung cancer.[23] Thus, exposure to asbestos in insulation workers, miners and millers, textile workers, shipyard workers, construction, and particularly demolition workers, is well recognized as increasing the risk of lung cancer. Exposure to polycyclic aromatic hydrocarbons is believed responsible for the increased risk in gas workers, coke oven workers, various groups of roofing workers and foundry workers. Exposure to radioisotopes, particularly to radon daughters, is recognized as causing lung cancer among various groups of miners,[24] especially uranium and fluorspar miners in Canada and the Colorado plateau in the United States, while the hematite workers in Great Britain are believed to have an increased risk, at least partially because of radiation exposure, as may many hard rock miners the world over. Nickel is now well recognized as a respiratory carcinogen having been first identified in South Wales,[25] Norway,[26] and Canada.[27]

Asbestos provides an example of the interaction of tobacco with an occupational factor. A cohort of 17,800 asbestos insulation workers was established by Selikoff on January 1, 1967. Up to December 31, 1974,[28] the ratio of observed to expected deaths from lung cancer was 3.2 for those with less than 20 years from first exposure and to 4.9 for those with more than 20 years from onset of exposure. A questionnaire was administered to this cohort on cigarette smoking and data on deaths up to December 31, 1972 have been analysed according to the smoking habits ascertained in the questionnaire. This indicated little increase in risk for those who had never smoked cigarettes or smoked pipes or cigars only, but nearly a six-fold risk for those who smoked cigarettes as well as those whose smoking habits were unknown. The latter group are believed to be largely a group of cigarette smokers.

As has been pointed out by Saracci[29] the data are compatible with an increased risk from asbestos exposure as well as an increased risk from cigarette smoking. This has now been confirmed by an updated analysis.[30] Selikoff has related the observed numbers of lung cancer to those expected on the basis of cigarette smoking specific rates in the long term study of cigarette smoking conducted by Hammond of the American Cancer Society. This results in a ratio of observed to expected for asbestos exposure approximating to five when one uses non-smoking individuals as the basis for expectation.

These data are compatible with those which might have been expected as is indicated in Table 4. Thus, the risk ratios for asbestos workers in general when compared to the general population approximate to five and to six when one compares cigarette smoking asbestos workers with the general population. However, when you calculate from Selikoff's published data the ratio for cigarette smoking asbestos workers compared to non-cigarette smoking asbestos workers, it reaches approximately 20 which is not incompatible with the ratios for cigarette smokers in general, or cigarette smokers who smoke 25 or more from the study of Doll and Peto.[15] As all the evidence appears to point to an interaction between cigarette smoking and asbestos exposure with a multiplicative interaction of the rates,[28] one could anticipate that the risk ratio for cigarette smoking asbestos workers compared to a non-cigarette smoking non-asbestos exposed general population group would approximate to 100. Selikoff's data seem to confirm this very well.[30]

In conclusion, in lung cancer we are dealing with one of the most clearly identified carcinogenic risk factors for any cancer in man, namely cigarette smoking. Although other factors are important and justify attention, such as occupational exposure and air pollution, a major reduction in lung cancer incidence and mortality is only going to be possible by a substantial shift in population exposure to cigarette smoking. In Canada, a reduction in smoking in males gives rise to cautious optimism[31] (Table 5) but the failure of this reduction to occur in females, particularly younger females, suggests it may be many years before the current increase in rates of lung cancer in women are brought to a halt. However, gains are being made: smoking is being banned in public places, non-smoking sections of airplanes, trains, buses are now usually available and regarded as a right in some countries, and a gradual change in the perception by the public of the tolerability of cigarette smoking appears to be occurring. It is thus possible that, in another two or three decades, we will begin to see the effect of a major impact on society's attitude towards smoking, in most technically advanced countries, in a reduction in both the incidence and mortality from lung cancer in both sexes.

b) Bladder Cancer

Bladder cancer has been known to be associated with cigarette smoking for some years,[12,14] though the earlier reports of the follow-up of British doctors[32] cast some doubt on this. The more recent report confirms an increase in the death rate from bladder cancer in smokers.[15] In a case control study of bladder cancer in Canada,[33] a strong association was confirmed in both males and females (Table 6). The population attributable risk for cigarette smoking was 61 per cent for males and 26 per cent for females. In this study an apparently reduced risk for filter cigarette smoking was found, and a risk for pipe smoking after controlling for cigarette smoking. There was, however, no evidence of interaction between the occupational causes of bladder cancer (attributable risk for high risk industries of eight per cent) and cigarette smoking in contradistinction to the evidence for lung cancer.

c) Laryngeal Cancer

Laryngeal cancer is well recognized as associated with cigarette smoking, alcohol consumption and a number of different occupational exposures.[34, 35] In a case-control study in Ontario, these associations have been confirmed but no evidence has been found for a reduced risk with smoking filter cigarettes.[36] However, there does seem to be an interaction between cigarette smoking and occupational exposures, especially asbestos.

d) Oral and Pharyngeal Cancer

These sites are well recognized as associated with tobacco and alcohol with marked synergy between them.[37] However, the authors are not aware of any reported interaction between smoking and occupation exposures.

e) Gastro-intestinal Cancer

Alcohol and tobacco act synergistically to increase the risk of oesophageal cancer.[38] Stomach cancer has so far been associated with smoking only in Japan,[39] but this may be an indication of another risk so far unidentified as the risk ratio is low (1.6) and no increased risk has been identified for stomach cancer in the large cohort studies. No association has so far been identified for colon or rectal cancer. Although all of these sites are associated with increased risk from asbestos exposure[40] there is no evidence of interaction between occupational exposure and tobacco consumption.

Pancreatic cancer has been increasing in Western countries since the last war, but in the last few years the increase may have come to an end. The association of pancreatic cancer with cigarette smoking is well recognized.[41] By the use of mathematical modelling approaches, Moolgavkar (personal communication, 1980) has calculated that a substantial proportion of pancreatic cancer may be attributable to cigarette consumption, and that much of the increase was due to this cause.

CONCLUSION

There is no question that a substantial and still increasing burden of human cancer is causally associated with tobacco and, particularly, cigarette consumption. Although there has been a recent U.S. publication suggesting an increase in cancer incidence is occurring in some sites not associated with tobacco usage,[42] it seems very probable that this increase is artifactual resulting from changes in cancer registration procedures rather than the impact of general environmental, and particularly chemical carcinogen exposures as some have claimed. It seems very probable, therefore, that overall cancer incidence and mortality could now be falling in both sexes were it not for cigarette smoking. It can be calculated from Canadian data that the average life expectancy of cigarette smoking males is 7 years less than that of non-smokers. It can also be determined that the lifetime risk of death from cigarette smoking associated cancer in males in Canada approximates to 15 per cent (after correcting for other causes of death) compared to less than three per cent in non-smokers. Most of this difference is due to lung cancer (12 per cent compared to less than two per cent). Nevertheless, the controversy which followed the release of a U.S. NCI-NIOSH document suggesting the possibility that over the next 20 years the proportion of cancer attributable to occupational exposures might increase to as much as 40 percent, indicated that many did not understand the concept of population attributable risk. Thus, in some populations it is possible for 90 per cent of lung cancer to be attributable to cigarette smoking, and also 40 per cent or more to occupational exposures. All this means is that the etiology of lung cancer is multi-factorial, and that at least 30 per cent is caused by the interaction of cigarette smoking and occupational exposure in the same individual, with a multiplicative increase in risk (as in Table 4), but with the implication that prevention of such cases is possible with the control of either cigarette smoking or occupational exposure.

Whether in Canada it is possible to mimic the approach recently adopted in Norway, where only non-smokers are permitted to work in some industries involving asbestos exposure, is debatable. However, it is clear that at least for larynx and lung cancer, control of cigarette smoking will have a much greater impact than attempts to control occupational exposures. What is still not clear is whether cessation of cigarette smoking will reduce the risk of subsequent lung cancer in those already exposed, or whether active prophylaxis[43] is the only option. Further research into these issues is urgently required.

References

1. Miller, A.B., Recent trends in lung cancer mortality in Canada, Canad. Med. Ass. Journal 116: 28-30, 1977.
2. Miller, A.B., Epidemiology and etiology of lung cancer. In Lung Cancer, 1980. Ed. H.H. Hansen and M. Rorth, Excerpta Medica Amsterdam, 1980, pp 9-20.
3. Waterhouse, J.A.H., Muir, C.S., Correa, P. and Powell, J. Eds. Cancer Incidence in five continents Volume III. IARC Scientific Publications No. 15, International Agency for Research on Cancer, Lyon, 1976.
4. Clemmeson, J. Statistical studies in the aetiology of malignant neoplasms. Act. Path. Microbiol. Scand. Suppl. 174:1: 277-342, 1965.

5. Coy, P., Grzybowski, S. and Rowe, J.F. Lung cancer mortality according to birthplace. Canad. Med. Ass. Journal 99: 476-483, 1968.
6. Dean, G. Lung cancer among white South Africans. Brit. Med. Journal 2: 852-857, 1959.
7. Dean, G. Lung cancer among white South Africans. Report on a further study. Brit. Med. Journal 2: 1599-1605, 1961.
8. Tokuhata, G.K. and Lilienfeld, A.M. Familial aggregation of lung cancer in humans. Journal Natl. Cancer Inst. 30: 289-312, 1963.
9. Springett, V.H. The beginning of the end of the increase in mortality from carcinoma of the lung. Thorax 21: 132-138, 1966.
10. Wald, N.J. Mortality from lung cancer and coronary heart disease in relation to changes in smoking habits. Lancet 1: 136-138, 1976.
11. Royal College of Physicians. Smoking and Health. Pitman Medical, London, 1962.
12. U.S. Public Health Service. Surgeon General's advisory committee on smoking and health. Smoking and Health. Public Health Service Publication No. 1103 Washington D.C., 1964.
13. Hammond, E.C. Smoking in relation to the death rates of one million men and women. Nat. Cancer Inst. Monograph 19: 127-204, 1966.
14. Kahn, H.A. The Dorn study of smoking and mortality among U.S. veterans: report on eight and one-half years of observation. Nat. Cancer Inst. Monograph 19: 1-125, 1966.
15. Doll, R. and Peto, R. Mortality in relation to smoking: 20 years' observations on male British doctors, Brit. Med. J. 2: 1525-1536, 1976.
16. Rose, G. and Hamilton, P.J.S. A randomised controlled trial of the effect on middle-aged men of advice to stop smoking. J. Epid. Comm. Hlth. 32: 275-281, 1978.
17. Lee, P.M. Has the mortality of male doctors improved with the reductions in their cigarette smoking. Brit. Med. J. 2: 1538-1540, 1979.
18. Russell, M.A.H., Wilson, C., Patel, V.A. *et al* Comparison of effect on tobacco consumption and carbon monoxide absorption of changing to high and low nicotine cigarettes. Br. Med. J. 4: 512-516, 1973.
19. Russell, M.A.H., Jarvis, M., Iyer, R. and Feyerabend, Relation of nicotine yield of cigarettes to blood nicotine concentrations in smokers. Br. Med. J. 280: 972-976, 1980.
20. Wynder, E.L. and Stellman, S.D. Impact of long-term filter cigarettes usage on lung and larynx cancer risk: a case-control study. J. Natl. Cancer Inst. 62: 471-477, 1979.
21. Doll, R., Gray, R., Hafner, B. and Peto, R. Mortality in relation to smoking: 22 years' observations on female British doctors. Br. Med. J. 280: 967-971, 1980.
22. Russell, M.A.H., Wilson, C., Taylor, C. and Baker, C.D. Smoking habits of men and women. Br. Med. J. 281: 17-20, 1980.
23. Fraumeni, J.F. Jr. Respiratory carcinogenesis: an epidemiologic appraisal. J. Natl. Cancer Inst. 55: 1039-1046, 1975.
24. Lundin, F.E. Jr., Lloyd, J.W., Smith, E.M. *et al*. Mortality of Uranium miners in relation to radiation exposure, hard-rock mining and cigarette smoking. 1950 through September 1967 Health Physics, 16: 571-578, 1969.
25. Doll, R., Matthews, J.D. and Morgan, L.G. Cancers of the lung and nasal sinuses in nickel workers: a reassessment of the period at risk. Brit. J. Indus. Med. 34: 102-105, 1977.

26. Pedersen, E., Hogetveit, A.C. and Andersen, A. Cancer of the respiratory organs among workers at a nickel refinery in Norway. Int. J. Cancer 12: 32-41, 1973.
27. McEwan, J.C. Cytological monitoring of nickel sinter plant workers. Annals N.Y. Acad. Sci. 271: 365-369, 1976.
28. Selikoff, I.J. and Hammond, E.C. Multiple risk factors in environmental cancer. In: 'Persons at High Risk of Cancer.' Fraumeni, J.F. Jr. ed. Academic Press, New York, 1975. pp 467-483.
29. Saracci, R. Asbestos and lung cancer: an analysis of the epidemiological evidence on the asbestos-smoking interaction. Int. J. Epid. 20: 323-331, 1977.
30. Selikoff, I.J. Occupational Cancer. In: Advances in Medical Oncology, Research and Education. Vol. I, Pergamon Press, Oxford, 1979.
31. Health and Welfare Canada. Smoking habits of Canadians, 1975. technical Report Series No. 7. Research Bureau, Non-medical use of Drugs Directorate, Health Protection Branch, Dept. of National Health and Welfare, Ottawa, 1977.
32. Doll, R. and Hill, A.B. Mortality in relation to smoking. Ten years' observations of British doctors. Br. Med. J. 1: 1399-1467, 1964.
33. Howe, G.R., Burch, J.D., Miller, A.B., Cook, G.M., Esteve, J., Morrison, B., Gordon, P., Chambers, L.W., Fodor, L. and Winsor, G.M. Tobacco use, occupation, coffee, various nutrients and bladder cancer. J. Natl. Cancer Inst. 64: 701-713, 1980.
34. Wynder, E.L., Covey, L.S., Mabuchi, K. and Mushinski, M. Environmental factors in cancer of the larynx. Cancer 38: 1591-1601, 1976.
35. Rothman, K.J., Cann, C.I., Flanders, D. and Fried, M.P. Epidemiology of laryngeal cancer. Epidemiol Rev. 2:195-209, 1980.
36. Burch, J.D., Howe, G.R., Miller, A.B. and Semenciw, R. Tobacco, alcohol, asbestos and nickel in the etiology of cancer of the larynx: a case-control study. J. National Cancer Institute 67: 1219-1224, 1981.
37. Rothman, K.J., The proportion of cancer attributable to alcohol consumption. Preventive Medicine, 9: 174-179, 1980.
38. Tuyns, A.J., Pequignot, G. and Abbatucci, J.S. Oesophageal cancer and alcohol consumption. Importance of type of beverage. Int. J. Cancer 23: 443-447, 1979.
39. Hirayama, T. Changing patterns of cancer in Japan with special reference to the decrease in stomach cancer mortality. In Origins of Human Cancer. Cold Spring Harbor Laboratory, Cold Spring Harbor, New York pp 55-75, 1977.
40. Miller, A.B. Asbestos fibre dust and gastro-intestinal malignancies. Review of literature with regard to a cause-effect relationship. J. Chron. Dis. 31: 23-33, 1978.
41. Fraumeni, J.F. Jr. Cancers of the pancreas and biliary tract. Epidemiologic considerations. Cancer Research. 35: 3437-3446, 1975.
42. Pollack, E.S. and Horn, J.W. Trends in cancer incidence and mortality in the United States, 1969-76. J. Natl. Cancer Inst. 64: 1091-1103, 1980.
43. Miller, A.B. Methodologic considerations for trials of lung cancer prophylaxis. CMA Journal 122: 776-779, 1980.

Table 1.

Change in cumulative incidence per 100 to age 75 in incidence of cancer of the lung reported by registries contributing to Volumes I and III of Cancer Incidence in Five Continents:

Registry	*Males*			*Females*		
	1959–62	*1968–72*	*% change*	*1959–62*	*1968–72*	*% change*
U.K. Liverpool	10.16	11.63	**14**	1.13	1.81	**60**
U.K. Birmingham	9.39	10.34	**10**	0.90	1.43	**59**
U.K. S. Metr.	9.20	9.54	**4**	1.22	1.79	**47**
Finland	8.48	10.07	**19**	0.50	0.54	**8**
FRG Hamburg	7.94	8.50	**7**	0.92	1.12	**22**
Hawaii Hawaiians	6.67	8.88	**33**	2.30	3.04	**32**
U.K. S. West	6.67	8.34	**25**	0.85	1.33	**56**
USA Connecticut	5.61	6.94	**24**	0.79	1.45	**84**
Hawaii Caucasians	5.42	6.67	**23**	0.92	2.30	**150**
Canada Manitoba	5.16	5.63	**9**	0.74	0.95	**28**
USA N. York State	4.94	7.03	**42**	0.55	1.32	**140**
Yugoslavia Slovenia	3.95	6.10	**54**	0.53	0.61	**15**
Canada Alberta	2.98	4.74	**59**	0.58	0.79	**36**
Canada Saskatchewan	2.82	4.62	**64**	0.33	0.83	**152**
Hawaii Japanese	2.55	3.19	**25**	0.60	0.89	**48**
Canada Newfoundland	2.40	4.41	**84**	0.47	0.35	**26**
Sweden	2.14	2.85	**33**	0.49	0.60	**22**
Colombia Cali	2.07	2.09	**1**	0.51	0.60	**18**
Japan Miyagi	2.01	2.46	**22**	0.66	0.95	**44**
Jamaica K & St. A.	1.87	2.81	**50**	0.32	0.64	**100**
Norway	1.78	2.98	**67**	0.35	0.55	**57**
Iceland	1.43	2.01	**41**	0.49	1.26	**157**
Singapore Chinese	1.37*	7.62	**456**	0.32*	2.28	**613**
Median Change	–	–	**25**	–	–	**48**

*Rates derived from 1950-61.

Table 2.

Death rate from lung cancer in males by smoking habits when last asked, British Doctors Study[15]

Tobacco Use Category		*Death Rate (Age standardized per 100,000)*
Non-smokers		10
Ex-smokers		43
Continuing smokers:		
	any tobacco	104
	pipe and/or cigar only	58
	mixed	82
	cigarette smokers only	140
	number smoked per day:	
	1–14	78
	15–24	127
	25 or more	251

Table 3.

Mortality from lung cancer in ex-cigarette smokers, British Doctors Study[15]

Compared to:	*Years since stopped smoking*				
	0	*Less than 5*	*5–9*	*10–14*	*15 or more*
Non-smokers (Ratio)	15.8	10.7	5.9	4.7	2.0
Continuing Cigarette Smokers (%)	100	68	35	25	11

Table 4.

Risk Ratios for Lung Cancer in Males

Group	*Referent*	*Risk Ratio*
Cigarette smokers (one or more/day)	Non-smokers	14.0
Cigarette smokers (25 or more/day)	Non-smokers	25.1
Asbestos workers	General population	4.9
Cigarette smoking asbestos workers	General population	5.7
Cigarette smoking asbestos workers	Non-smoking asbestos workers	21.2
Cigarette smoking asbestos workers	Non-smoking general population	(100.0)

Table 5.

Change in percentage of cigarette smokers, Canada.

	Males		*Females*	
	1965	*1975*	*1965*	*1975*
Regular smokers	54.6	43.3	31.2	31.4
Smokers of 25 plus cigarettes/day	5.8	4.7	1.3	2.0

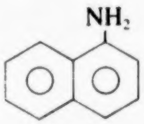
Table 6.

Relative risk for bladder cancer in terms of total lifetime consumption of cigarettes (source – ref. 33).

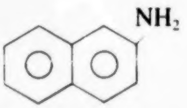
Total Lifetime Consumption (packs)	*Males*	*Females*
0.0	1.0	1.0
Up to 10,000	2.5	2.0
10,000 – 20,000	4.4	3.3
Greater than 20,000	5.8	

APPENDIX D
Case History – β-Naphthylamine

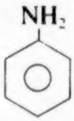
A variety of organic dyes were introduced into commerce during the latter part of the 19th century. Many of these were based on aromatic amines used first as crude mixtures and later as partially purified compounds. Some, but not all, of these amines turned out to be powerful carcinogens and induced bladder tumours in hundreds of workers before the situation was brought under control. The pages that follow relate the saga of some of these amines with emphasis on β-naphthylamine. Since the plants that produced this compound were also involved in the manufacture of other amines, particularly aniline, benzidine and α-naphthylamine, some of the effects of these agents will also be mentioned.



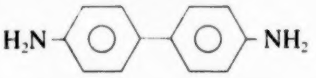
α-naphthylamine
(1-naphthylamine)



β-naphthylamine
(2-naphthylamine)



aniline



benzidine

Background

Until 1856 the dyes and colouring materials used on fabrics were either organic materials of natural origin (indigo, wood, cochineal and the like) or mineral colours such as chrome yellow and prussian blue. This changed when Perkin in 1856 (whilst trying to synthesize quinine) discovered a fine purple dye and was diverted from his original objective. For reasons of economy he turned to the use of so-called 'benzene' obtained from the distillation of coal tar as a starting material. The 'benzene' was nitrated to form 'nitrobenzene' which was reduced to 'aniline' and then oxidized to give the mauve pigment. Shortly afterwards other investigators learned how to treat this 'aniline' to produce a magnificent magenta dye (fuchsine) and a new industry was born. The synthesis of a wide range of other organic dyes swiftly followed. Manufacturing experience showed that the colours produced often varied widely depending upon the source of the 'benzene'. This turned out to be a consequence of the fact that the so-called 'benzene' produced by the crude, processes of the time was, in reality, a rich mixture of various aromatic hydrocarbons. Indeed, the boiling point of the crude 'benzene' was often as high as 130°C (pure benzene boils at 80°C) indicating that it contained a good deal of material having higher molecular weights than pure benzene. In the course of the next 30 years the true nature of the 'benzene' was realized and the industry moved to the use of more highly purified starting materials. At the same time new colours were developed from an ever increasing selection of uncoloured starting materials and in 1889 β-napthylamine was first manufactured on a large scale and eventually was used in the manufacture of 21 different dyes. Originally, this compound was prepared by the addition of ammonia to β-naphthol and isolated as a salt. The salt paste was dried on trays and powdered in open mills. Thus, workmen were heavily exposed to dusts. When vacuum distillation of the free base (as opposed to the salt form) was introduced as a purification step, a much more serious hazard arose because β-napthylamine vapour was carried through the plant and thus extended the risk to all workers rather than only to those engaged in handling the substance. Indeed, the workplace was so permeated by the vapour that β-naphthylamine sublimed out on the faces, hair and clothes of the workmen. The contaminated air was breathed for long periods so that a great deal of the amine was undoubtedly absorbed.

In Britain, France, Italy and the U.S. small dye-works, employing rather few workers developed, but in Germany, particularly around Frankfurt, and to a smaller extent in Switzerland, large dye-works developed during the last decades of the 19th century.

Health Effects

In 1895 Rehn, a Frankfurt surgeon, noted that three of his patients with bladder cancer all worked in the same dye factory and, indeed, had worked together making fuchsine in the same shed. Rehn suggested that their working environment might have caused their tumours. By 1906 Rehn published a survey which listed a total of 38 cases of bladder cancer amongst 'aniline' workers in seven different factories. Others suggested that the high incidence of bladder cancer observed by Rehn might have had a geographical rather than occupational origin but this view was discredited after the discovery of bladder cancer amongst workers in the Swiss dye industry around Basle. By 1913 over 100 cases of occupational bladder cancer were known and the German chemical industry, now conscious of the hazard, built new, rationalized factories and introduced protective measures.

During World War I, the allied countries were cut off from the products of the German chemical industry on which they had come to depend and, thus stimulated, their own industries expanded rapidly. The problem of bladder cancer was forgotten and the German and Swiss experience was repeated in Britain, France, Italy and U.S. This occurred, in Britain at least, despite the fact that the relation between the dye industry and bladder cancer in Germany was known to the Factory Inspectorate as early as 1912.

The first report of bladder cancer among British chemical workers was published in 1926 (12 fatal cases). Despite an ever increasing number of cases, no concerted effort was made by British industry until after World War II even though the Swiss manufacturers decided in 1939 to abandon the synthesis of β-napthylamine. However, in 1946 the Association of British Chemical Manufacturers set up a scientific committee for the guidance of research work, aiming at a) information on causation, b) improved diagnostic methods, c) improved methods of testing for causative agents and d) information likely to improve preventative techniques. Dr. R.M.A. Case was appointed to head the study. The results of this 'classic' study are summarized in the next section.

The 'Case' Study[1]

This study was a statistical analysis of the mortality from bladder cancer in the British chemical industry. Particularly illuminating were the results for 2,466 men known to be, or to have been, engaged in the manufacture or use of aniline, benzidine, β-naphthylamine and α-naphthylamine and in which 242 cases of bladder cancer had been discovered by 1950 (i.e., 10 per cent of the group exposed). Careful analysis of this group showed further that the risk of bladder cancer in this occupational group could be determined for workers exposed only (or at least primarily) to benzidine, α-naphthylamine, β-naphthylamine, or to have been exposed to more than one of these materials. These risks relative to that for men in the general population were:

Aniline	No significant increase
Benzidine	19X
α-naphthylamine	16X
β-naphthylamine	61X
Mixed exposure	33X

In addition, as shown in Figure 1, the occupational bladder cases occurred at much younger ages than those in the general population and the age of onset of bladder cancer was directly related to the age at entry into the occupation (Fig. 2) with the *average* time of onset being 17.8 years after first exposure, i.e., the average induction time or latent period was 17.8 years. However, there was much variation in the latent period with some cases occurring within five years while others were not detected until 45 years after first exposure.

Figure 1 - The age at death

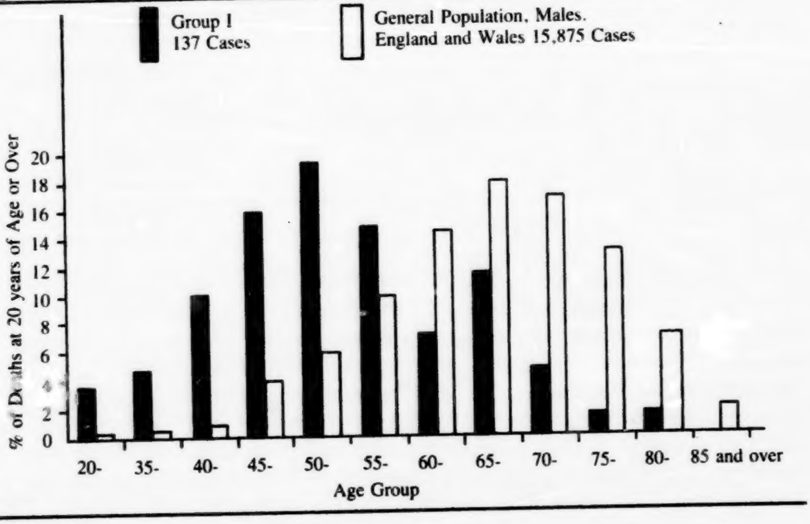
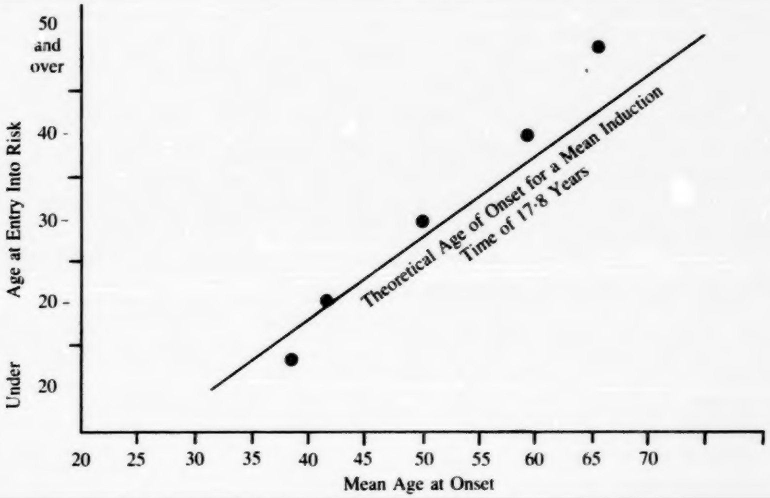


Figure 2



It is also instructive to consider some additional data reported in 1958 by M.H.C. Williams,[2] describing the probable fate of 78 men who worked as distillers of benzidine and β-naphthylamine under poor conditions (Table 1).

Table 1

Progressive increase of bladder tumours among 78 aromatic amine distillers with increasing length of exposure

Length of latent period in years	*Length of exposure in years*					
	Up to 1	*1*	*2*	*3*	*4*	*5 and over*
	Percentage of workers with tumours					
Up to 5	0	0	0	0	0	0
10	0	0	0	0	0	11
15	0	17	22	0	10	45
20	4	17	22	40	30	69
25	9	17	22	70	70	88
30	9	17	48	70	80	94

From: M.H.C. Williams, 1958.[1]

This table was constructed using mortality data for the group at a time when 35 of the 78 had died from bladder cancer, and from life tables. Clearly, exposure for less than one year led to cancer in nine per cent of the individuals but no tumours developed in this group until after 15 to 20 years. Furthermore, as the dose (as judged by years of exposure) increased the percentage of the individuals affected also increased and the latent period was shortened. However, even in the high exposure group in which 94 per cent of the men would have eventually died from bladder cancer, ***no tumours appeared during the first five years.***

Animal Studies

Early attempts to induce tumours in rodents with β-naphthylamine gave negative results — an outcome which confused the issue and led some to question the role of this compound as an occupational hazard. However, in a preliminary report published in 1938, Heuper *et al.*[3] reported that administration of amine to dogs for 90 weeks induced bladder carcinomas. This result has been confirmed in several subsequent studies. In addition, β-naphthylamine has now been shown to induce bladder cancer in hamsters, rabbits (although the response was weak) and monkeys. It produces liver tumours in the mouse but in the rat and rabbit, it has little effect.[4]

Other studies have shown that it is not β-naphthylamine itself that initiates the process of tumour induction but that the active agent is an oxidized product (metabolite) formed in the liver and excreted in the urine. Thus, the cells that line the bladder are more or less continually bathed in the activated carcinogen — a fact which helps to explain why bladder is the 'target tissue' for these compounds.

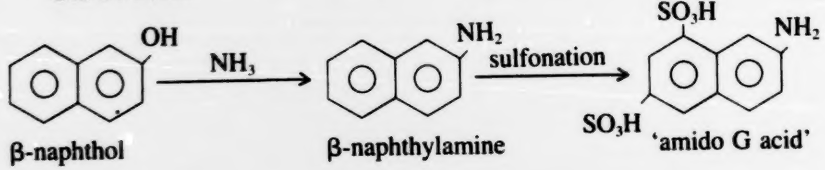
Subsequent History of Use

In 1952 the British chemical industry ceased to make or use β-naphthylamine, but in the U.S. manufacture continued until early 1973. In 1955 the total production amounted to 581,000 kg.

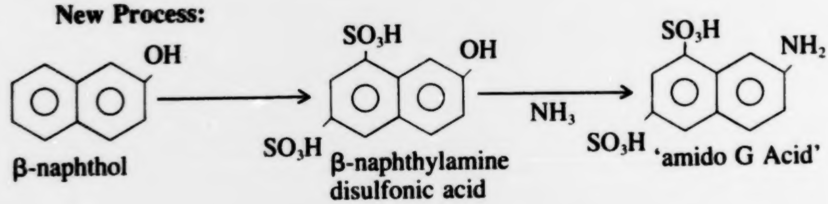
The presence, use and manufacture of β-naphthylamine in factories is prohibited in the U.K. and its use is regulated in the U.S. under regulations established by the Occupational Health and Safety Administration. In Ontario β-naphthylamine is regarded as a known carcinogen to which no exposure should be permitted.

In general, it has been possible to substitute non-carcinogenic materials for β-naphthylamine in the synthesis of the final products and to avoid its use as a synthetic intermediate, e.g.:

Old Process:



New Process:



It is of significance that while pure as well as commercial β-naphthylamine and benzidine induce tumours, it appears that α-naphthylamine is very much less potent as a carcinogen. Indeed, there is no convincing evidence that pure α-naphthylamine is a hazard to human health,[5] and that the industrial hazard associated with the use of commercial α-naphthylamine (risk of bladder cancer 16 times that of general population) was in fact a consequence of contamination by the β-isomer which made up several per cent of the material.

Many instances are also known in which chemicals prepared from β-naphthylamine contained enough of the amine (a contaminant present because the chemical reactions involved did not go to completion) to constitute a hazard to workers or consumers.

Similarly, the initial suggestion of Rehn that aniline caused tumours was incorrect. These tumours were undoubtedly caused by the presence of other amines, including β-naphthylamine, in the crude materials used in the early industry. There is no evidence that aniline by itself is carcinogenic.[6]

References

1. Case, R.M.A., Hosker, M.E., McDonald, D.B. and Pearson, J.T. Tumors of the urinary bladder in workmen engaged in the manufacture and use of certain dye stuffs in the British Chemical Industry. I. The role of aniline, benzidine, α-naphthylamine and β-naphythylamine. British J. Industrial Med., 1954 *11* 75.
2. Williams, M.H.C. Occupational tumors of the bladder. In: R. Raven ed. Cancer, Butterworth, London, Vol. III p. 337–380 [1958].
3. Heuper, W.C., Wiley, F.H., and Wolfe, H.D. (1938). Experimental production of bladder tumors in dogs by administration of β-naphthyl amine. Journal of Industrial Hygiene, Vol. 20, p. 46.
4. IARC Monograph on the evaluation of carcinogenic risk of chemicals to man, *4* 97–119, [1974].
5. IARC Monograph on the evaluation of carcinogenic risk of chemicals to man, *4* 87–111, [1974].
6. IARC Monograph on the evaluation of carcinogenic risk of chemicals to man, *4* 27–39, [1974].

ADMINISTRATION

Legal Mandate of The Advisory Council

Section 10, the Occupational Health and Safety Act.

Advisory Council on Occupational Health and Occupational Safety
10.—(1) There shall be a council to be known as the Advisory Council on Occupational Health and Occupational Safety composed of not fewer than twelve and not more than twenty members appointed by the Lieutenant Governor in Council on the recommendation of the minister.

Term of office of members
2) The members of the advisory council shall be appointed for such term as the Lieutenant Governor in Council determines and shall be representative of management, labour and technical or professional persons and the public who are concerned with and have knowledge of occupational health and occupational safety.

Chairman and vice-chairman
3) The Lieutenant Governor in Council shall designate a chairman and a vice-chairman of the advisory council from among the members appointed.

Vacancies
4) The Lieutenant Governor in Council may fill any vacancy that occurs in the membership of the advisory council.

Remuneration and expenses
5) The remuneration and expenses of the members of the advisory council shall be determined by the Lieutenant Governor in Council and shall be paid out of the moneys appropriated therefor by the legislature.

Powers of advisory council
6) The advisory council, with the approval of the minister, may make rules and pass resolutions governing its procedure, including the calling of meetings, the establishment of a quorum, and the conduct of meetings.

Idem
7) The function of the advisory council is and it has power,
a) to make recommendations to the minister relating to programs of the ministry in occupational health and occupational safety; and
b) to advise the minister on matters relating to occupational health and occupational safety which may be brought to its attention or be referred to it.

Annual report
8) The advisory council shall file with the minister not later than the 1st day of June in each year an annual report upon the affairs of the advisory council.

Idem
9) The minister shall submit the report to the Lieutenant Governor in Council who shall cause the report to be laid before the assembly if it is in session or, if not, at the next ensuing session. 1978, c. 83, s. 10.

Primary objective of advisory council

To advise the Minister of Labour on all matters relative to occupational health and safety in Ontario.

Secondary objectives of advisory council

1. To ensure as far as is possible that the policies and programs in occupational health and safety effectively minimize the risks to health and safety in all workplaces in Ontario.
2. To ensure as far as is possible that knowledge about occupational health and safety is available to management, labour and the public and that it is understood by them.
3. To assist in promoting and establishing mechanisms involving management and labour to solve problems in occupational health and safety.
4. To ensure as far as is possible that there is appropriate manpower training and development for the occupational health and safety field.

5* To review periodically the effectiveness of the policies and programs implemented to achieve secondary objectives 1 to 4.

Terms of reference of advisory council

1. To make recommendations on matters referred to it by the minister, submitted to it by interested parties or pursued by the council on its own initiative.
2. To advise the minister on programs in the field of occupational health and safety.
3. To advise the minister on policies, principles and procedures used in standard setting and in the development of guidelines to be used by the government.
4. To review and make recommendations to the minister on the introduction of new substances such as chemicals into the workplace.
5. To review and make recommendations on the detection, measurement and control of occupational health and safety hazards in the workplace.
6. To review and make recommendations about the arrangements for occupational health and safety for groups and areas where there are no formal health and safety programs or the programs are judged to be inadequate.
7. To advise the minister on priorities for research and development in occupational health and safety.
8. To advise the minister on priorities for manpower training and development in the field of occupational health and safety.
9. To prepare an annual report to the minister, which shall include the advisory memoranda, recommendations of the council and the government response.

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*added June 1980

Meetings of The Advisory Council

April 21, 1981
May 12, 1981*
June 9, 1981
July 31, 1981
September 8, 1981
October 13, 1981**
November 30, 1981***
January 26, 1982
February 9, 1982
March 9, 1982

Special Meetings of Council

June 26, 1981	to deal with draft lead regulation
November 30, 1981	meetings at Kitchener with representatives of health and safety committees of several selected industries
December 1, 1981	
March 30, 1982	to deal with draft vinyl chloride regulation

* Discussions with deputy minister and staff followed by dinner meeting with minister.

** Discussions with deputy minister and staff.

***Executive meeting of council at Kitchener.

TASK FORCES

TASK FORCES OF ADVISORY COUNCIL ON OCCUPATIONAL HEALTH AND OCCUPATIONAL SAFETY

TASK FORCE ON PRINCIPLES AND PROCEDURES FOR SETTING STANDARDS AND REGULATIONS

Terms of Reference
To establish guidelines by which the council can determine the appropriateness of the principles, policies and procedures used in setting the standards and regulations in occupational health and safety in Ontario. To include such things as the development of the regulations and public input about those regulations.

Membership
Mr. L. Heard—Chairman
Dr. E. Mastromatteo
Mr. J.M. More
Mr. R. Wilson

Meetings Held	*Reports to Council*	*Resulting in*
May 8, 1981	May 12, 1981	Advisory Memorandum
June 9, 1981	June 9, 1981	81 - I
July 30, 1981	June 26, 1981	81 - III
September 4, 1981	July 31, 1981	
November 16, 1981	September 8, 1981	
	October 13, 1981	
	November 30, 1981	
	February 9, 1982	
	March 30, 1982	

TASK FORCE ON LITERACY AND OCCUPATIONAL HEALTH AND SAFETY

Terms of Reference

i) To examine the extent of the problem of illiteracy in the workforce.
ii) To identify the effects of illiteracy on the effectiveness of occupational health and safety.
iii) To propose recommendations on how problems associated with illiteracy and occupational health and safety can be resolved in the short term and the long term.

Members

Council Members
Mr. W.A. Barnes
Mr. E.A. Waddell – Acting Chairman from January, 1982 during absence of Chairman
Mr. P.A. Fisher

Others
Dr. James Draper – OISE – Chairman
Dr. R.J. Adams – McMaster University
Mr. J. Pearpoint – Frontier College
Mr. G. Wilson – UAW

Liaison Representative
Dr. D. Maudsley – Ministry of Education
Ms. S. Pratt – Ministry of Citizenship and Culture

Meetings Held
April 23, 1981
May 21, 1981
July 14, 1981
September 17, 1981
October 20, 1981
December 22, 1981

TASK FORCE ON WOMEN AND OCCUPATIONAL HEALTH AND SAFETY

Terms of Reference

i) To review the occupational health and safety problems of women at work.
ii) To examine the issue of susceptibility.
iii) To examine whether existing occupational health and safety standards and procedures take into account special needs, if any, of women.
iv) To propose recommendations to the council on any matters identified in the study.

Members

Council Members
Dr. G.J. Stopps—Chairman
Mrs. N. Caldbick
Mr. J.M. More

Others
Mrs. S. Bobier – Ortho Pharmaceutical (Canada) Ltd.
Mr. R. DeMatteo – Ontario Public Service Employees' Union

Meetings Held
April 1, 1981
October 14, 1981
March 31, 1982

SPECIAL ADVISORY COMMITTEE ON CARCINOGENS

Terms of Reference

i) To examine the principles governing the regulation development process to determine how the process can effectively and efficiently identify, prioritize and regulate carcinogens.
ii) To propose recommendations on the policies and and principles governing the development of regulations for carcinogens.

Members
Dr. J.F. Mustard – Chairman
Dr. M. Farber – Banting Institute
Dr. A.B. Miller – Faculty of Medicine, University of Toronto
Dr. D. McCalla – Dept. of Biochemistry, McMaster University
Dr. J.E. Till – Ontario Cancer Institute

Meetings Held	*Reports to Council*	*Resulting in*
April 27, 1981	June 9, 1981	Report of the Special Advisory Committee
June 2, 1981	January 26, 1982	
December 4, 1981	February 9, 1982	
February 5, 1982	March 9, 1982	

TASK FORCE ON THE ROLE OF HEALTH SURVEILLANCE AND HEALTH SCREENING IN OCCUPATIONAL HEALTH PROGRAMS

Terms of Reference

i) To identify the risks, benefits and costs of health surveillance and health screening in occupational health programs.
ii) To review the laws and procedures governing health surveillance and health screening with regard to the rights and duties of employers, employees, government and the professions.
iii) To make recommendations to the council on policies and principles governing health surveillance and health screening in occupational health programs.

Members

Council Members
Dr. A.D. Wolfson—Chairman
Dr. J.W. Charters
Mr. J.M. More
Dr. E. Mastromatteo

Others
Prof. T. Ison – Osgoode Hall Law School
Dr. D. Sackett – McMaster University
Ms. S. Acheson – OFL (resigned February 1982)
Ms. J. Robertson – Canadian Airline Employees' Association – Appointed March 1982

Meetings Held
May 14, 1981
November 20, 1981
December 18, 1981
January 15, 1982
February 12, 1982
February 19, 1982
March 18, 1982

TASK FORCE ON POTENTIAL NEW HAZARDS – PHASE TWO

Terms of Reference

i) To review whether the procedures governing introduction of new processes and equipment in the workplace adequately take into account occupational health and safety issues.

ii) To review the voluntary standard setting procedures governing the design of new equipment and processes.

iii) To review whether procedures for setting standards for personal protective equipment are adequate to ensure that the most cost-effective protective equipment is available.

iv) To propose recommendations to the council on the above issues.

Members

Council Members
Dr. E. Mastromatteo—Chairman
Mr. G.J. Samson
Mr. L. Heard
Mr. E.A. Waddell

Others
Dr. T.M. Fraser – University of Waterloo

Meetings Held
May 8, 1981
July 10, 1981
August 7, 1981
December 11, 1981

SPECIAL TASK GROUP ON THE ROLE OF THE SAFETY ASSOCIATIONS

At the December 1980 meeting of council a special task group was set up to prepare an advisory memorandum on the future role of the safety associations.

Membership

Dr. T.F. Mustard—Chairman
Mrs. N. Caldbick
Dr. J.W. Charters
Dr. R.D. Fraser
Mr. C.G. Pilkey
Mr. M.A. Taschereau
Mr. E.A. Waddell

Meetings Held	*Reports to Council*	*Resulting in*
April 10, 1981	April 21, 1981	Advisory Memorandum 81 - II and letter of clarification dated February 11, 1982
July 20, 1981	July 31, 1981	
July 28, 1981	September 8, 1981	
August 19, 1981	October 13, 1981	
February 3, 1982	February 9, 1982	
February 8, 1982		

TASK FORCE ON FINANCIAL INCENTIVES IN THE OCCUPATIONAL HEALTH AND SAFETY FIELD

Terms of Reference

i) To determine whether organizations faced with relatively large financial costs in complying with occupational health and safety regulations should be eligible for grants or other appropriate financial incentives.
If the answer to (i) is yes, then:

ii) To analyse the various types of financial incentives that might be made available to organizations faced with relatively large occupational health and safety costs.

iii) To make recommendations to council on which type of financial incentives would be most appropriate to assist organizations meet their occupational health and safety costs.

iv) To make recommendations to council on the procedures that should be utilized to determine when an organization would qualify for such incentives.

Members

Council Members
Dr. A.D. Wolfson—Chairman
Dr. R.D. Fraser
Mr. P.A. Fisher
Mr. C.G. Pilkey

Others
Mr. I. Rosen C.A.
Mrs. V. Kempston-Darkes – G.M. Canada, Oshawa

Liaison Representatives
Mrs. N. Bardecki – Ministry of Treasury and Economics
Mr. H.D. Forbes – Ministry of Industry and Trade Development
Dr. J.A. Donnan – Ministry of the Environment

Meetings Held	*Reports to Council*	*Resulting in*
May 14, 1981	November 30, 1981	Advisory Memorandum 81 - IV
July 9, 1981	March 9, 1982	
September 9, 1981		
September 10, 1981		
October 9, 1981		
November 6, 1981		
December 16, 1981		
February 11, 1982		

TASK FORCE ON THE POSSIBLE HEALTH HAZARDS OF VISUAL DISPLAY UNITS (VDUs)

Terms of Reference:
To evaluate the available information on the possible hazards to human health associated with the use of visual display units.
The term health to include discomfort, degradation of visual acuity and excessive fatigue as well as better-defined disease states, such as cataracts.

Membership:

Council Member
Dr. G.J. Stopps—Chairman

Others
Mr. R. DeMatteo – Ontario Public Service Employees' Union
Dr. S. Garnett – McMaster University
Dr. E. Kaegi – CIL
Ms. J. Keene-Moore – Bell Northern Research
Dr. J. Parker – University of Toronto
Dr. J. Purdham – Canadian Centre for Occupational Health and Safety
Prof. R. Roberts – McMaster University
Dr. S. Stuchly – University of Ottawa

Meetings Held
November 2, 1981
November 25, 1981
March 1, 1982

TASK FORCE ON THE IMPLEMENTATION OF THE OCCUPATIONAL HEALTH AND SAFETY ACT

Terms of Reference:
i) To review the application and interpretation of the Act and regulations, with particular reference to such issues as:
   - the right to refuse work
   - the role of government
   - legal interpretations
   - responsibilities regarding health and safety information

ii) To examine the functioning of the joint health and safety committees, including the matter of access to information.
iii) To review the application and implementation of the designated substances regulations.
iv) To make appropriate recommendations.

Members:

Council Members
Dr. A. D. Wolfson - Chairman
Mr. W. A. Barnes
Mr. J. Duffy
Mr. P. A. Fisher
Mr. J. Gill
Mr. M. A. Taschereau
Mr. E. A. Waddell

Others
Mr. K. Glassco – Energy and Chemical Workers Union (Polysar Ltd.)
Dr. E. Kaegi – CIL
Mr. J. N. Lockington – DOFASCO
Mr. T. Meagher – OFL
Prof. R. Prichard – University of Toronto - Faculty of Law
Mr. C. Schmidt – United Rubber Workers of America (Uniroyal Ltd.)
Prof. K. Swinton – University of Toronto - Faculty of Law

Meetings Held

Task Force	*Sub-committee*
January 5, 1982	January 28, 1982
February 10, 1982	February 19, 1982
March 8, 1982	March 18, 1982

TASK FORCE ON THE INTERPRETATION OF HEALTH EFFECTS DATA AND THE ROLE OF ECONOMIC ANALYSIS IN THE STANDARD-SETTING PROCESS

Terms of Reference:

i) a) To examine the principles and procedures which should be employed to [i] evaluate health effects data and [ii] classify and rank health effects studies.
   b) To examine [i] the appropriate role for economic analysis in the standard-setting process and [ii] the kinds of economic information (if any) which should be collected and analysed as part of the process for developing regulations.
   c) To determine whether common principles can be applied to the interpretation and analysis of health effects and economic cost data.
ii) To examine the manner in which health effects and economic information should be integrated in the regulation of hazardous substances.
iii) To make recommendations to council in respect to these issues.

Members:

Council Members
Dr. R. D. Fraser—Chairman
Mr. L. Heard
Dr. E. Mastromatteo

Others
Dr. E. Farber – University of Toronto
Mr. A. L. Gladstone – Ministry of Labour (ex-officio)
Ms. L. Jolly – Consultant
Prof. R. Roberts – McMaster University
Nominee from – Canadian Centre for Occupational Health and Safety

Meetings Held

January 19, 1982	March 5, 1982
February 19, 1982	March 19, 1982

APPENDICES

APPENDIX A

Injuries, Permanent Disabilities and Fatalities Receiving First Payment of Compensation in 1980 by Year-End 1981, Classified by Nature of Injury.

Nature of Injury	*Major Permanent Disabilities*[1]		*Other Disabling Injuries*[2]		*Fatalities*[3]	
	No.	*%**	*No.*	*%*	*No.*	*%*
Amputation or enucleation	8	4.28	866	0.53	1	0.40
Asphyxia, strangulation or drowning	0	0.00	1	0.00	9	3.59
Burn, scald – heat	0	0.00	4,352	2.64	11	4.38
Concussion, brain – cerebral	0	0.00	407	0.25	1	0.40
Contusion, crushing, bruise – intact skin	9	4.81	18,665	11.33	142	56.57
Cut, laceration, puncture – open wound	5	2.67	20,809	12.63	0	0.00
Dislocation	0	0.00	671	0.41	0	0.00
Electric shock, electrocution	1	0.53	274	0.17	11	4.36
Fracture	3	1.60	8,650	5.25	1	0.40
Hernia, rupture	0	0.00	1,894	1.15	0	0.00
Scratch, abrasion – superficial wound	2	1.07	6,112	3.71	0	0.00
Sprain, strain	80	42.78	46,672	28.32	0	0.00
Multiple injuries	3	1.60	873	0.53	5	1.99
Occupational injuries, unspecified	58	31.02	48,719	29.57	6	2.39
Occupational injuries, NEC[4]	0	0.00	61	0.04	0	0.00
Burn – chemical	1	0.53	1,201	0.73	0	0.00
Tuberculosis only	0	0.00	7	0.00	0	0.00
Tuberculosis and pneumoconiosis	0	0.00	0	0.00	0	0.00
Contagious and infectious disease, NEC	0	0.00	186	0.11	0	0.00
Dermatitis	4	2.14	711	0.43	0	0.00
Freezing, frost-bite – environmental cold	0	0.00	27	0.02	0	0.00
Hearing loss or impairment[5]	0	0.00	830	0.50	0	0.00
Heat – sunstroke – environmental heat	0	0.00	13	0.01	1	0.40
Bursitis	0	0.00	6	0.00	0	0.00
Synovitis, tenosynovitis	1	0.53	323	0.20	0	0.00
Inflamation, irritation, NEC	0	0.00	298	0.18	0	0.00
Poisoning, systemic	2	1.07	730	0.44	3	1.20
Silicosis	1	0.53	41	0.02	3	1.20
Asbestosis	1	0.53	8	0.00	1	0.40
Pneumoconiosis, NEC	2	1.07	55	0.03	0	0.00
Radiation effects	0	0.00	1,167	0.71	0	0.00
Caisson's disease	0	0.00	2	0.00	0	0.00
Occupational illness, NEC	6	3.21	93	0.06	56	22.31
Non-personal damage	0	0.00	55	0.03	0	0.00
Other-preventive measures[6]	0	0.00	4	0.00	0	0.00
Total[7]	187	99.97	164,783	100.00	251	100.01

*Percentages are rounded to the nearest one-tenth.

1. This includes those who had received their first payment of compensation in 1980 and were receiving a pension as of December 31, 1981. 'Major' is arbitrarily defined as a permanent disability rating of 50% or greater. Lump sum payments are excluded.
2. Receiving first payment of compensation for the Workmen's Compensation Board in 1980.
3. Fatalities include those who had received their first payment of compensation in 1980 and were dead by year end 1981. These figures are different from those in the Workmen's Compensation Board's record of fatalities. The difference is explained by different definitions of fatality and by different time frames used.
4. NEC stands for 'Not Elsewhere Classified.'
5. The official WCB figure for hearing loss for 1980 is 950.
6. Under section 53 of the *Workmen's Compensation Act*, certain high risk individuals, whose health may be impaired by continued exposure to silica, asbestos or radiation may apply for and receive compensation while undergoing retraining. See the *Report of the Royal Commission on the Health and Safety of Workers in Mines* for further information.
7. Due to rounding, percentages do not add up to 100 per cent.

APPENDIX B

Fatality Frequency Rates per Million Man-hours and Numbers of Fatalities for Major Industries in Ontario 1977, 1978, 1979 and 1980[1]

	1977 Number of Fatalities[2] attributed to:			1978 Number of Fatalities attributed to:			1979 Number of Fatalities attributed to:			1980 Number of Fatalities arrtibuted to:		
Industry	*Occupational Disease*	*Trauma*	*Fatalities per Million Man-hours*	*Occupational Disease*	*Trauma*	*Fatalities per Million Man-hours*	*Occupational Disease*	*Trauma*	*Fatalities per Million Man-hours*	*Occupational Disease*	*Trauma*	*Fatalities per Million Man-hours*
Agriculture	0	7	0.10	1	6	0.10	1	4	0.07	1	5	0.08
Forestry	1	5	0.33	1	8	0.45	0	6	0.27	0	13	0.61
Mining, Quarrying and Oil Wells	21	18	0.45	12	11	0.32	9	7	0.24	28	24	0.74
Manufacturing	11	37	0.02	11	43	0.03	25	51	0.03	18	43	0.03
Construction	4	46	0.18	1	35	0.14	2	40	0.18	4	35	0.19
Transportation, Communication and Other Utilities	0	24	0.18	1	22	0.17	2	26	0.21	2	26	0.21
Trade	2	8	0.01	0	6	0.01	0	13	0.02	0	10	0.01
Community, Business and Personal Services	0	11	0.01	2	16	0.01	0	9	0.01	3	8	0.01
Public Adminstration	1	3	0.04	5	8	0.14	4	4	0.10	2	3	0.07
Other (Fishing)	0	0	0	0	0	0	0	1	0.90	0	0	0.00
All (Schedule 1 only)	41	158	0.05	34	155	0.04	43	161	0.03	58	167	0.05
All (Schedule 2 included)	44	181	—	36	187	—	52	183	—	64	187	—

1. Data for 1977-1979 have been reworked using a revised definition of disease. Diseases are defined as ICD #9 < 800.0. The 1977 data are slightly different from those shown in last year's annual report.
2. Fatalities include those who received their first payment of compensation in 1977, 1978, 1979 and 1980 and were dead by year-end 1978, 1979, 1980 and 1981 respectively. These figures are different from those in the Workmen's Compensation Board's record of fatalities. The difference is explained by different definitions of fatality and by different time frames used.

Source: Research Branch, Ministry of Labour. The WCB rate number groups have been allocated to the industry categories by the Research Branch in compiling the data.

APPENDIX C
Compensated Work Injury Frequency Rate per Million Man-hours for Major Industries in Ontario, 1970–1980*

Industry	*1970*	*1971*	*1972*	*1973*	*1974*	*1975*	*1976*	*1977*	*1978*	*1979*	*1980*
Agriculture	32.65	32.34	30.69	31.29	31.25	28.41	33.81	32.28	33.52	34.84	34.03
Forestry and Logging	82.57	83.05	98.38	107.19	98.75	79.35	70.30	79.05	85.91	79.46	77.11
Mining, Quarries and Oil Wells	47.96	40.60	41.64	49.92	58.93	63.66	68.32	63.65	53.24	47.12	55.40
Manufacturing	31.74	29.31	31.65	33.79	35.18	32.09	34.00	33.90	34.05	32.02	36.71
Construction	66.99	61.51	63.66	60.72	58.07	51.77	64.02	62.11	62.16	65.57	67.64
Transportation and Communication	57.11	55.37	55.70	58.37	55.56	50.93	55.27	55.71	57.16	64.05	62.03
Trade, Wholesale and Retail	19.42	17.93	18.82	18.82	18.73	16.92	18.05	18.09	18.35	18.96	18.29
Services											
Hospital	11.53	11.42	11.92	11.33	11.11	9.67	19.73	19.84	19.88	21.81	22.85
Teaching	9.57	8.03	8.42	8.75	9.41	8.56	9.16	9.23	8.82	9.78	9.94
All	11.42	10.84	11.65	10.96	10.47	9.36	10.29	10.57	10.61	11.53	12.01
Public Administration	30.28	31.31	34.66	31.13	28.61	27.71	30.43	31.70	31.11	32.32	32.88
Others (Fishing)	62.76	38.99	60.60	51.92	37.53	40.85	33.51	37.49	38.20	24.25	32.98
All Industries (Schedule 1)	28.66	26.76	28.10	28.72	28.95	25.73	29.02	28.40	28.07	27.91	29.48

*1980 data are provisional.

Source: Research Branch, Ministry of Labour — April 1981, from Workmen's Compensation Board '*Final Accident Frequency and Cost Rate by Rate Number Report*' for each year. The WCB rate number groups have been allocated to the industry categories by the Research branch in compiling the data.

APPENDIX C-1
Number of Compensated Work Injuries for Major Industries in Ontario, 1970–1980*

Industry	*1970*	*1971*	*1972*	*1973*	*1974*	*1975*	*1976*	*1977*	*1978*	*1979*	*1980*
Agriculture	2154	2049	1900	2154	2218	2059	2145	2178	2419	2481	2565
Forestry and Logging	1908	1651	1815	2118	2256	1540	1206	1449	1721	1784	1645
Mining, Quarries and Oil Wells	4497	4014	3682	4111	5084	5654	6234	5480	3877	3183	3970
Manufacturing	55034	51648	59580	68381	75043	66663	70809	68676	69161	79000	73327
Construction	18362	17750	18178	18306	19026	16959	18933	16791	15538	15162	13687
Transportation and Communication	6310	6114	6727	7328	7639	6880	7421	7511	7703	8525	8167
Trade, Wholesale and Retail	10265	9494	10715	11414	12593	11752	12932	12835	13243	14472	13960
Services											
Hospital	4207	4236	4560	4722	5096	5144	5150	5500	5592	6278	1050
Teaching	900	445	542	588	624	585	904	1180	1121	1172	6701
All	6280	6410	7460	7841	8222	8072	9190	9687	10028	11414	11939
Public Administration	1497	1881	2319	2264	2232	2431	2615	2892	2829	2694	2436
Others (Fishing)	53	32	53	49	34	35	28	31	36	27	34
All Industries (Schedule 1)	111,467	105,724	117,531	129,276	140,112	127,774	137,567	134,212	133,268	146,192	139,481

*1980 data are provisional.

Source: Research Branch, Ministry of Labour — April 1981, from Workmen's Compensation Board '*Final Accident Frequency and Cost Rate by Rate Number Report*' for each year. The WCB rate number groups have been allocated to the industry categories by the Reasearch Branch in compiling the data.

APPENDIX D

Injuries Receiving Compensation in 1979 by Occupation Ranked in Descending Frequency per 100 Employees Covered by the Workmen's Compensation Board of Ontario

Occupation[1]	*Disabling Injuries 1979*[2]	*Estimated Employment Covered by WCB (000)*[3]	*Estimated Injuries per 100 Employees Covered by WCB*
Forestry, Logging	1,582	9	17.58
Machining	18,234	141	12.93
Mining, Quarrying	1,663	15	11.09
Material Handling	9,832	96	10.24
Transport Equipment Operation	12,962	137	9.46
Processing	12,871	141	9.13
Construction	16,954	218	7.78
Product Fabricating	26,286	418	6.29
Service	17,113	445	3.85
Other Crafts	1,941	52	3.73
Fishing, Hunting	34	1	3.4
Medicine and Health	4,932	147	3.36
Agriculture	2,816	99	2.84
Social and Related	639	52	1.23
Sales	4,737	396	1.20
Clerical	9,669	685	0.98
Natural Science, Engineering	1,113	138	0.81
Teaching and Related	928	145	0.64
Artistic, Recreational	292	61	0.48
Managerial, Administrative	962	299	0.32
Religion	1	9	0.01
Not Stated	4,618	—	—
Occupations, NEC[4]	15,552	—	—
	165,731[5]	3,704	

1. Taken from *Canadian Classification and Dictionary of Occupations*. See Appendix D-2.
2. Receiving first payment from the Workmen's Compensation Board of Ontario in 1979. Schedules 1 and 2.
3. Derived from Statistics Canada Labour Force Survey 1979. It is estimated that WBC covers approximately 92.5% of the employed labour force. Estimates for 'Service' exclude domestics, babysitters and barbers and those for 'Agriculture' combine the number of owner operators and the number of paid workers and employees.
4. NEC stands for 'Not Elsewhere Classified.'
5. WCB Annual Report has 165,456.

Source: Research Branch, Ministry of Labour, report dated February 11, 1982.

APPENDIX D-1

Injuries Receiving Compensation in 1980 by Occupation Ranked in Descending Frequency per 100 Employees Covered by the Workmen's Compansation Board of Ontario

Occupation[1]	*Disabling Injuries 1980*[2]	*Estimated Employment Covered by WCB (000)*[3]	*Estimated Injuries per 100 Employees Covered by WCB*
Forestry, Logging	1,555	10	15.55
Machining	16,991	122	13.93
Mining, Quarrying	2,291	21	10.91
Material Handling	10,474	101	10.37
Transport Equipment Operation	12,507	140	8.93
Processing	12,373	150	8.25
Construction	15,878	216	7.35
Product Fabricating	25,569	411	6.22
Service	17,716	454	3.90
Fishing, Hunting	38	1	3.80
Medicine and Health	5,206	154	3.38
Agriculture	2,882	99	2.91
Other Crafts	1,881	54	2.24
Clerical	9,364	701	1.34
Sales	4,791	396	1.21
Social and Related	680	60	1.13
Natural Science, Engineering	1,072	156	0.69
Teaching and Related	884	133	0.66
Artistic, Recreational	317	59	0.54
Managerial, Adminsitrative	866	313	0.28
Religion	4	7	0.06
Not Stated	8,568	—	—
Occupations, NEC[4]	13,314	—	—
	165,221	3,758	

1. Taken from *Canadian Classification and Directory of Occupations*. See Appendix D-2.
2. Receiving first payment from the Workmen's Compensation Board of Ontario in 1980. Schedules 1 and 2.
3. Derived from Statistics Canada Labour Force Survey 1980. It is estimated that WCB covers approximately 92.5% of the employed labour force. Estimates for 'Service' exclude domestics, babysitters and barbers and those for 'Agriculture' combine the number of owner operators and the number of paid workers and employees.
4. NEC stands for 'Not Elsewhere Classified.'

Source: Research Branch, Ministry of Labour, report dated February 11, 1982.

APPENDIX D-2

Selected Occupations Defined by Subgroup from the Canadian Classification and Dictionary of Occupations

1. *Mining* and quarrying including oil and gas field operations have the following occupational groups included: foremen, rotary well-drilling, other rock and soil drilling, blasting, cutting, handling and loading, labouring and other elemental work, and not elswhere classified (NEC).

2. *Machining* and related occupations have these groups included: foremen *metal machining*: tool and die making, machinist and machine tool setup, machine tool operating; *metal shaping and forming*: forging, sheet metal workers; welding and flame cutting, boilermakers, platers and structural metal workers; foremen *wood machining*: wood pattern making, wood sawing and related work, wood sanding; foremen *clay, glass and stone and related materials*: cutting and shaping, abrading and polishing; foremen *other machining* and related work, engravers and etchers, filing, grinding, buffing, cleaning and polishing work, inspecting, testing, grading and sampling occupations.

3. *Forestry* includes these groups of occupations: foremen forestry and logging, forestry conservation, timber cutting, log hoisting, sorting, moving, labouring, forestry and logging NEC, log inspecting, grading and scaling.

4. *Materials handling* has these occupations grouped together: foremen materials handling NEC, hoisting operations NEC, longshoremen, stevedores and freight handlers, materials handling equipment operators NEC, packaging, labouring in materials handling work.

5. *Processing* occupations are composed of: *mineral ore*: treating, crushing and grinding, mixing, filtering, melting and roasting; *metal processing*: smelting, converting and refining, metal heat treating, metal rolling, moulding, coremaking and metal casting, metal extruding and drawing, plating and metal spraying: *clay, glass and stone* furnacemen and kilnmen, separating, grinding, crushing and mixing, forming; *chemicals, petroleum, rubber, plastic and related materials:* mixing and blending, filtering, straining and separating, distilling, subliming and carbonizing, coating and calendarizing; *food, beverage and related*: flour and grain milling, baking, confectionery making, slaughtering and meat cutting, canning, curing and packing, fish canning, curing and packing, fruit and vegetable canning, preserving and packing, milk processing, sugar processing, beverage processing; *Wood*: sawmill sawyers, plywood making, wood treating; *Pulp and paper making*: cellulose preparing, papermaking and finishing; *Textiles*: fibre preparing, spinning, winding, weaving, knitting, bleaching, finishing; *Other*: tobacco, hide and pelt. Foremen, inspecting, testing and grading, elemental labour in all above groups.

6. *Transportation and Equipment* operating occupations have the following sub-groups: air transport, railway transport, water transport, motor transport and the specific occupations in each.

7. *Construction* has these sub-groups: excavating, grading and paving, electrical power, lighting and wire communications equipment erecting, installing and repairing and construction trades—carpenters, brick and stone masons, concrete finishing, plasterers, painters and paper hangers, insulating, roofing, pipe-fitting, structural metal erectors, glazers. Foremen inspecting, testing, grading and sampling, and elemental labour are included in the above where appropriate.

8. *Product fabricating* classification is composed of: metal products; electrical, electronic and related equipment; wood products; textile, fur and leather products; rubber, plastic and related products; mechanics and repairmen except electrical; and other: jewellery and silverware, marine craft, paper products, and painting and decorating.

Ontario
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